



Wearable Devices and mHealth

How Consumer Devices are Impacting Healthcare

GlobalData Report | March 2018



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Wearables and mHealth have significant opportunities for growth

- **In this report, the focus is on the wearable devices which combine computing power and wireless communication to provide data relating to healthcare.**

Wearable devices are autonomous devices, using sensors and wireless data transmission for real-time feedback, which can be attached to the body or worn. They are used to track many conditions and biological parameters, and in some cases aid in diagnosis of disease. This report covers the consumer-focused wearable devices and mHealth apps with potential for clinical utility in the US market.

- **Miniaturization of complex technologies has allowed their use in wearable devices.**

Processing, imaging and sensor technology have improved at a vast rate in recent years to accommodate the rise in smartphones, becoming sufficiently advanced, miniaturized and inexpensive that it can be worn discreetly on the body. In addition, the prevalence of smartphones allows wearables to operate partly as an extension of a users phone, enabling more complex functionality through mobile applications.

- **The potential market for healthcare wearables is vast, however vendors must convince consumers of their benefits to boost adoption by mainstream consumers.**

One wearable device in particular, the smartwatch, has achieved widespread adoption by consumers, with 12% of US adults owning a smartwatch in 2017. To grow as a healthcare device, companies must provide physicians with evidence of clinical value.

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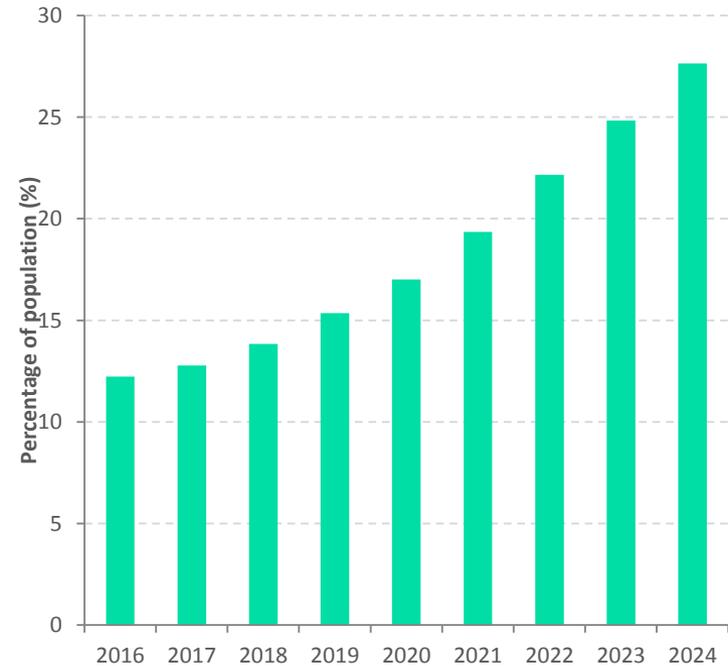
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Smartwatches are the most commercially successful wearable device to date

Since the release of the Pebble in 2012, sales of smartwatches have increased dramatically. In 2017, an estimated 12% of Americans own a smartwatch, with growth expected to continue throughout the next 5 years.

Already, technology companies with successful smart watches are looking toward the healthcare market as a key opportunity for growth. Many devices offer heart rate monitoring, alongside the more traditional step tracking and GPS tracking for fitness purposes. Some companies are also beginning to look into incorporating oxygen saturation measurements in an effort to appeal to the healthcare sector.

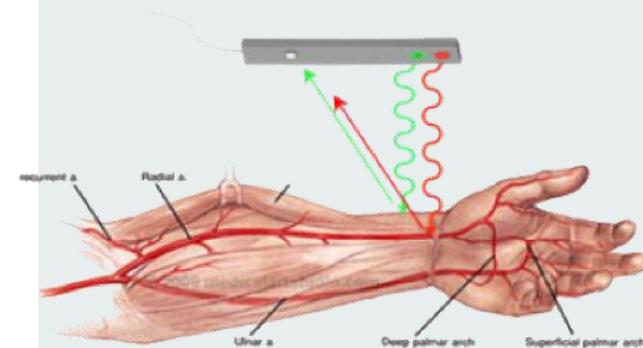
Smartwatch Ownership Is Expected to Increase



Smartwatches typically use an optical sensor to track parameters such as heart rate

Optical sensors are ideal as they are able to make non-invasive measurements, typically using a technique called photoplethysmography (PPG). Often these sensors use green light, which reduces signal distortion when interpreting the return signal; however, the light is not able to penetrate deep into the tissue, providing a limit to the type of data that can be accurately collected.

One alternative being explored is the use of red light sensors, which could allow measurement of more physiological parameters. Several manufacturers reportedly have red sensors incorporated into their devices, but they do not yet seem to be functional, possibly due to the increased complexity involved in analyzing data from red light. It is likely that future devices will contain sensors for a range of wavelengths, enabling tracking for wider applications in healthcare.



The Apple Watch has dominated smartwatch sales since its release, and currently has the most function in healthcare

- **With the recent release of the Series 3, Apple is focusing more on the potential healthcare market.**
In November 2017, Apple launched the Heart Study app, which uses the Apple Watch's heart rate sensor to identify users who may be experiencing atrial fibrillation.
- **Apple Watch sales now outperform Rolex.**
Although Apple does not release sales figures for its watch, CEO Tim Cook revealed in Q3 2017 that Apple now has higher watch sales than Rolex.
- **Apple's ResearchKit and CareKit platforms facilitate diagnosis and monitoring of disease using Apple Watch.**
ResearchKit is a software medical platform launched in 2015. While initially for iPhone use, apps are beginning to utilize data from an Apple Watch. For example, EpiWatch aims to predict the onset of seizures.



Fitbit released their first connected smartwatch in 2017

- **Fitbit maintains high brand recognition, with particular focus on users seeking to be more active.**
Fitbit has had less of a focus on the medical market, instead developing their brand as a fitness tracker. The integration with social media has led to a large user base, which enables data mining to improve future products.
- **The Fitbit Ionic is the company's first true smartwatch.**
As technology has improved, consumers are demanding more from their devices. As a result, Fitbit has now fully entered the smartwatch market with the Ionic.
- **Fitbit announced before release that the Ionic would contain a SpO₂ blood oxygen sensor.**
Despite reports in August, the new device has no mention of this feature. It appears the technology is not yet sufficiently accurate for release, but could become a key feature of devices in the next 2–5 years.



Garmin has a diverse portfolio of wearables

- **Garmin has a wide variety of devices accommodating different activities and price points.**
Much like Fitbit, the focus has been on fitness tracking and lifestyle. While Garmin's devices often contain better features, Fitbit has greater brand recognition and consumer reach.
- **Its history of GPS-based products in the marine, outdoor, aviation, and fitness markets has helped Garmin withstand challenges from competition.**
The diversity of products offered provides insulation to changes in the consumer wearables market.
- **Garmin's open philosophy enables watches to pair with sensors from multiple brands, in addition to having an open platform for app development.**
This enables individuals or companies to extend the features and functionality of their wearables.



Nokia acquired Withings in May 2016, and has a focus on maintaining health and disease prevention

- **Digital health is a key long-term component of Nokia's resurgence in consumer electronics.**

Nokia has rebranded Withings products, including a smartwatch, smart scale, and app. Despite a slight backlash to the app rebrand, Nokia is aiming to establish itself as a key player in the wearables market.

- **The Nokia Steel smartwatch has a classic design, with most of the features only accessible through the app.**

Unlike many of its competitors, Nokia has maintained the analogue watch face on its smartwatch. This feature is likely to appeal to a wider user base, particularly those less accustomed to pervasive technology in everyday life, although it limits the use of the watch without an accompanying smartphone. It also enables Nokia to avoid competing directly with Apple on software.



Philips has entered the healthcare wearables market with a specific focus on the older generations

- While competitors are currently competing on their function as a fitness tracker, Philips has entered the market with healthcare firmly in mind.

The Philips health watch is one of a suite of connected health devices, including a thermometer, blood pressure monitor and body analysis scales. While it also tracks activity levels, there is a clear focus on health, measuring heart rate, respiration rate and VO2 max.

- Philips' health watch has been classified as a class 2 medical device by the FDA.

In waiting for an FDA listing before release, Philips is laying the groundwork to compete with consumer-focused competitors in the healthcare market. While many companies are focusing on a younger target market, Philips is looking towards a new market of users: those purchasing a wearable on the advice of their doctor.



“Philips is not in the world of fitness... We’re in the connected health space, and target consumers who are at risk of chronic diseases.”

- Eline de Graaf, Director for Philips Personal Health Solutions

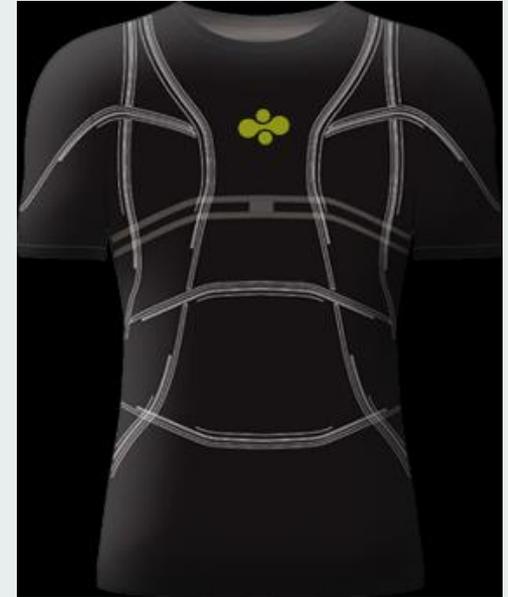
Google's healthcare company has produced a smartwatch, but it is not expected to enter the market for up to 5 years

- **Currently named the Study Watch, Verily's smartwatch is being used for research only and is not for sale.**
It is expected that the watch will be on sale after studies have been concluded, with a focus on monitoring health.
- **Project Baseline is an effort to develop a reference point for health, with potential use in future products.**
In partnership with Duke University and Stanford Medicine, Verily is undertaking an observational study of approximately 10,000 participants over four years. It will use the Study Watch for part of the data tracking.
- **Verily is also using the watch in a multi-year study around Parkinson's disease.**
There has been significant investment by Verily into healthcare. GlobalData expects a firm move into the healthcare market within five years.



There are few devices as wearable as clothing, however smart clothes have not yet seen widespread adoption

- **Companies including Samsung, Levi's, and numerous start-up companies are developing smart clothing.** Clothing varies from yoga leggings and bras to smart sleeves and tops, measuring heart rate, activity levels, and even enabling payments.
- **Smart clothing is likely to become more popular in the sportswear market.** Tracking performance is a large business in professional sports, and these technologies are beginning to be seen commercially. GlobalData expects the value of smart clothing to increase significantly in the coming years.
- **However, current technology is not sufficient for smart clothing to cross the barrier into the healthcare sector.** Insights from key opinion leaders suggest that adoption of smart clothing will be limited in the medical sector.



“Smart clothing... I can see how it’s great for sportspeople, but I don’t see it being used clinically until the technology improves.”

- Key Opinion Leader

There are many possibilities for wearable devices, which may be worn on any part of the body

- **Wearable products such as patches and other devices have entered the market for patient monitoring.**

While this report focuses on consumer-based products, it is expected that hospital-based products will become increasingly common in the next five years, particularly in data management and remote patient monitoring.

- **Chest straps are being used by athletes.**

As technology in smartwatches has improved, the difference between wrist-worn wearables and chest straps in measuring heart rate has decreased. Although chest straps are still in use, they are not typically used for healthcare purposes.

- **Other wearable devices are predominantly used for fitness, with some other non-health applications.**

There are many wearables available purely for fitness purposes, for example trackers in shoes, which are not expected to cross the barrier into healthcare. Smart jewelry is a new market to emerge, but most efforts are focused on security, for example a ring granting access to a building.

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Healthcare is changing as an aging population demands more from physicians

- **Burden on healthcare services is increasing.**

Populations are growing worldwide. By 2030, there will be approximately 71 million Americans ages 65 years and older, accounting for roughly 20% of the US population, according to the CDC. This is in part leading to a shift in the healthcare paradigm toward preventative care and early diagnosis, with wearable technologies expected to play a role. The demand for new technologies in healthcare management is leading to growth in the wearables market.

- **Availability of data trends can provide context for physicians.**

The ability to constantly monitor health has potential to become a key tool in maintaining health. Currently, patients with inconsistent symptoms are difficult to diagnose without invasive or cumbersome technologies if they appear asymptomatic in the clinic. This problem could be alleviated with wearable technologies that are capable of providing accurate data. Additionally, providing simple information such as weight and blood pressure over time is clinically more meaningful than one measurement in the clinic. Companies such as Fitbit, Nokia, and Philips are bringing out connected scales and blood pressure monitors, providing clinically actionable data for physicians.

Although currently limited, the potential for data trends in patients over extended periods of time is driving growth and investment into wearable devices

“If a patient is asymptomatic in clinic but clearly has something wrong, right now we do very invasive things, maybe give them a Holter monitor for a few days, implanting something under the skin, so for patients like this, a wearable device would be very helpful if it could accurately measure heart rhythms. If we could have data for a month or two months and we could get a better idea if somebody is having arrhythmias. But that would only be for a very small patient group.”

- Key Opinion Leader

“If I have a patient with atrial fibrillation who is on medication, if they can track their heart rate while exercising, I can see if the medication keeps their heart rate in control and doesn’t spike very fast. That can be done with today’s apps, but it is a pretty limited application.”

- Key Opinion Leader

“Some data we ask for is tracking weight and blood pressure, but that is more data reporting than automatically from a device.”

- Key Opinion Leader

Technology is improving as companies invest in wearable technologies

- **Sensor technologies have improved.**

The rise of wearable electronics and miniaturized sensor technologies, combined with “big data” analysis tools, has enabled the rise of viable wearable devices (Tricoli et al., 2017). The reliability of data collected from wearable technologies has improved even while the size of such sensors has decreased to the point where companies are attempting to put them into more everyday objects. One example is Verily’s well-publicized smart contact lens, which aims to detect glucose levels for diabetics.

- **Large existing technology companies are heavily investing in healthcare R&D.**

One challenge that has arisen for existing smartwatch vendors is the lack of a clear use case for regular computing. In general, apps are better experienced on a phone and the ability to see notifications is often not sufficient to convince consumers to purchase costly wearable devices. Health has therefore become a key target market for technology companies to transform smartwatches from a luxury into a necessity. Apple is currently using Research Gate for clinical trials, and many companies are heavily investing in research to be able to provide further clinical data from their smartwatches for patients.

As people become more connected, health is increasingly viewed as wellness

- **Health is no longer considered the absence of disease.**
A major trend in the US population is the desire to take control of their own health. This has manifested in patients demanding access to their medical records as well as an increased interest in maintaining their own health. Wearable technologies are tapping into this view of health as wellness, which is driving demand for these devices.
- **There is a growing number of healthcare-related apps and connected devices**
Developers are making large numbers of healthcare applications for smartphones that are compatible with wearable devices; most estimates put the number of healthcare apps at over 30,000. As more apps are developed, wearables are able to perform more functions, driving increased demand.

“One application will not be in the disease model, but in the health model. This will not be as regulated as a market for treatments, but society is getting more aware of the concept of health being healthy and not just the absence of disease... I see these watches being a health follow-up tool rather than a disease follow-up tool.”

- Key Opinion Leader

Until smartwatches sell themselves on their healthcare benefits, the market potential is smaller than it could be

- **The potential market for pure fitness use is limited.**
Fitbit published lower growth in 2017 than 2016, which could be due to slowing interest in simple fitness bands. Consumers are demanding more from smartwatches, so manufacturers must demonstrate their additional value beyond their fitness benefits. Additionally, the potential market size for fitness is smaller than for healthcare.
- **High cost of smartwatches is a barrier to consumers.**
The wearables market is reliant on consumer purchases. Price is a key value driver for consumers and is one of the leading factors influencing purchase. As a result, the high cost of most wearables, typically over \$150, is a barrier to a large portion of the population. Unless prices decrease or insurance companies offer wearable devices, these consumers will not be able to afford smartwatches.

“The number of people who are able to afford these high price products by themselves for comfort level is very low... If you were to develop these [devices] and the patients were to pay for it themselves then it will be a very small market, as many patients will not be able to pay for it. The insurance companies will then look at it and say ‘why should we pay for it when they can get these tests in clinic’, and won’t offer it.”

- Key Opinion Leader

The data currently produced by smartwatches are not clinically actionable

- **Smartwatches currently have limited clinical use**

Although many can see the potential benefits of wearable devices that are able to monitor patients and even aid remote diagnosis, the technology is currently not at a level that is useful in all cases. Patients are keen to take data to physicians from their wearables, but currently there is very little clinical value to the data collected. In order to reach the full market potential of wearables, further research into clinical utility is required in order to fully break into the medical space. If smartwatches were able to provide clinically actionable data, physicians may begin to encourage their use.

“Today, just getting somebody’s heart rate data is not usually actionable... we don’t actually use it clinically. Physical activity, sure, if they’re not exercising it may be a sign that they are getting more congested and maybe they’ll get sick, but it’s not current practice that we automatically get that data and act on it.”

- Key Opinion Leader

“Yes we do get [wearables] data but I truly don’t know what to do with it today.”

- Key Opinion Leader

“With sleep pattern tracking, there is no intervention that is linked to that.”

- Key Opinion Leader

Improvements are required to reach market potential

- **Data is perceived to be of poor quality.**

Although the reliability of data provided by wearables has improved even in the last two years, there is still a perception among both physicians and consumers of poor data quality. One strategy to circumvent this is by registering the device with the FDA as a medical device, as has been done by Philips. Alternatively, companies can publish more data from studies demonstrating the accuracy and reliability of their data.

- **Healthcare technology is not able to progress at the typical speed of other technologies.**

The end goal of some vendors is the ability to market wearables with clinical value. However, FDA approvals are often lengthy and could undermine the value of new technology if vendors must wait a year for approval before entering market. Apple is reported to have approached the FDA, possibly to arrange special treatment of the Apple Watch in the approval process.

“One issue is what is the fidelity of the data, how reliable is it as opposed to the more invasive assessment that we are used to doing. I assume if the FDA is approving these devices they have looked into it and this data is pretty reliable, so the issue moves from reliability to what to do with it clinically.”
- Key Opinion Leader

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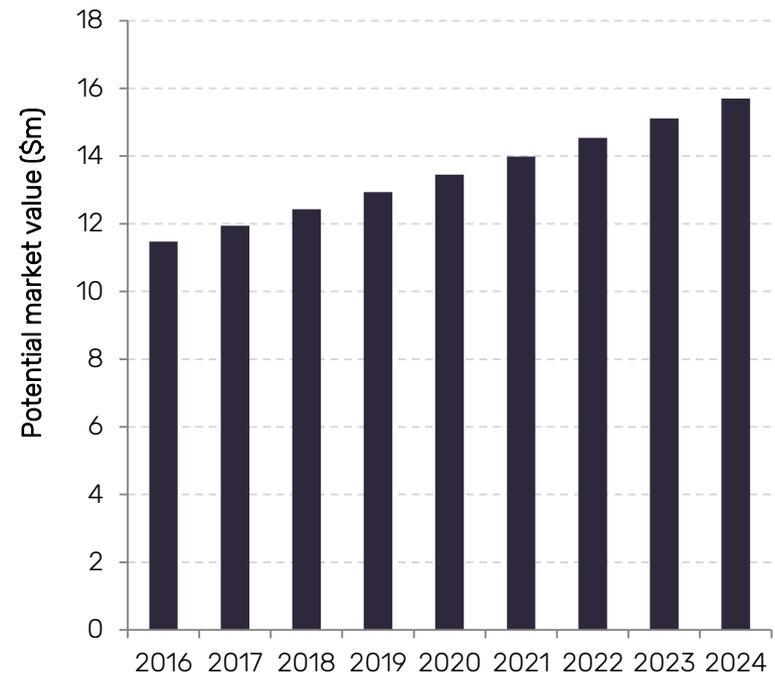
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Wearables often track heart rate, and many companies are looking to expand their cardiology offerings

- **Cardiac health is a high-profile issue.**
Almost half of Americans (47%) have at least one of three major risk factors for heart disease (Fryar et al., 2012). It is a key area of interest to consumers, leading to a drive for more cardiology-related wearables.
- **Many wearable devices include a heart rate monitor.**
Although physicians have mixed opinions about the clinical utility of heart rate data, it is a common feature of wearable devices. Originating from fitness applications, many manufacturers are researching technology improvements for more sophisticated data collection to be used clinically.

Cardiology mHealth Potential Market Size



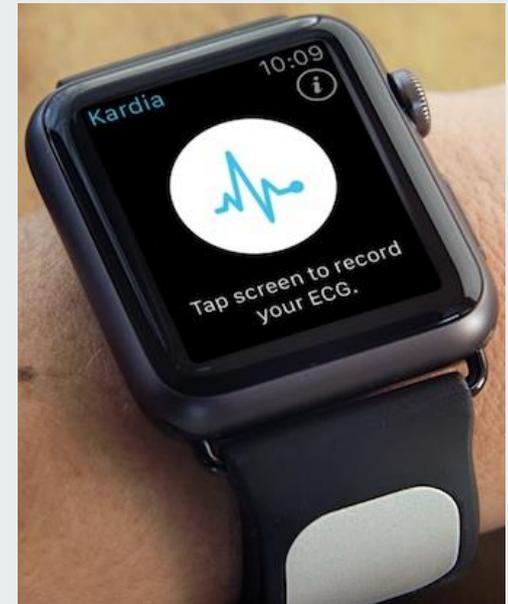
Apple and Stanford University's School of Medicine have launched the Apple Heart Study to investigate the possibility of monitoring patients with atrial fibrillation

- **Detection and monitoring of atrial fibrillation is a key market for heart rate monitors.** Many device manufacturers are aiming to provide clinically actionable data from their wearables, ideally using existing sensors. Although clinicians have responded skeptically to the utility of heart rate data provided by wearables, monitoring of irregular heartbeats such as in atrial fibrillation has been raised by key opinion leaders as a potential benefit of wearable devices. Currently, if atrial fibrillation is suspected a patient will undergo an ECG during a clinic visit. If a patient is asymptomatic during this visit they may be fitted with a Holter monitor, typically for 24–48 hours.
- **The Apple Heart Study is likely to result in new functionality for the next-generation Apple Watch.**

The most recent Apple Watch contains an improved heart-rate monitoring system, including warning users if their heart rate spikes when not exercising. The Apple Heart Study will be expanding on this feature, using data from the Apple Watch to analyze arrhythmias, likely with a view to diagnosis or monitoring, particularly as the company has been working closely with the FDA throughout this endeavor.

AliveCor makes portable ECG monitors, and recently received FDA approval for an attachment to the Apple Watch

- **AliveCor's EKG Kardia Band is the first medical-grade accessory for the Apple Watch.**
The existing KardiaMobile device attaches to an iPhone and requires users to hold the phone with two hands for 30 seconds to take a reading. The Kardia Band enables users to take readings with one thumb on a sensor on the strap using the with the Kardia app opened. During the recording, users are encouraged to use the microphone to record additional symptoms which can be sent to their physicians.
- **AliveCor has positioned itself as a patient monitoring device aimed at consumers.**
The target market of AliveCor is consumers who are ready to take more responsibility for their own healthcare. The device is equally marketable to the "worried well" and as a follow-up tool used by cardiologists.



While many wearable device manufacturers have focused on wrist-worn devices, Qardio offers chest-based measurements

- **The QardioCore is another wearable ECG monitor aimed at providing clinically relevant information to consumers.** While many chest straps are designed purely for fitness, QardioCore is hoping to position itself as a strong player in the healthcare market. While AliveCor requires user input for each recording, Qardio distinguishes itself by capturing continuous ECG data.
- **Chest-worn devices are often less favored by consumers.** While wrist-worn devices are able to take the place of a regular watch, chest-based wearable devices must overcome any initial resistance to perceived discomfort in regular life. QardioCore's slick design may alleviate some concerns; however, as miniaturization of technology continues, GlobalData predicts consumers will continue to demand smaller, more discreet devices.



iRhythm's Zio XT Patch continuously monitors heart rhythms in a wireless device about the size of a bandage

- **The Zio XT is able to be worn discreetly for up to 14 days.**
While Holter monitors are typically worn for 24–48 hours, the ZIO XT is designed to be worn for two weeks, enabling monitoring of a broader range of daily activity. A prospective comparison of Holter monitors with the Zio Patch showed that while they were comparable for 24 hours, the longer duration of recordings on the Zio Patch resulted in more cardiac events being recorded (Barrett et al., 2014). Additionally, the participants found the patch more comfortable and preferred it to the Holter monitor. Overall, smaller sizes and improved outcomes for patients are expected to drive the use of smaller cardiac monitors such as the Zio.
- **The Zio Service maintains proprietary analysis of results, but does not require an additional appointment to remove.**
The Zio patch is intended to be applied to the patient by a clinician, but is simple enough to be removed without medical supervision. The patch must then be posted to iRhythm for analysis.



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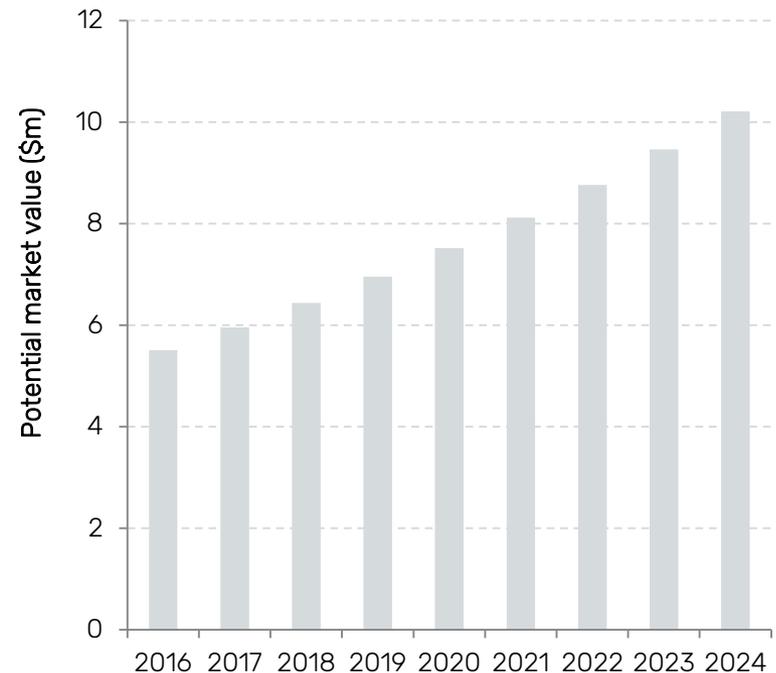
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Prevalence of diabetes is growing worldwide

- **Diabetes is a growing market for wearables.**
In 2017, approximately 30,000 US citizens are living with diabetes (International Diabetes Federation, 2017). This number is expected to grow over the coming years, creating a large potential market.
- **Management of glucose levels is a constant concern for diabetics.**
The development of Continuous Glucose Monitoring (CGM) sensors, wearable minimally invasive devices, has modernized glucose monitoring in recent years. Diabetics are able to wear a small patch for several consecutive days, preventing the need to self-monitor using finger prick measurements.

Diabetes mHealth Potential Market Size



Modern CGMs are facilitating diabetes management for patients

- **Abbott's new FreeStyle Libre device enables patients to forego finger prick tests entirely.**
The device consists of a transcutaneous sensor measuring glucose levels every 15 minutes in interstitial fluid. Unlike many other CGMs, patients are not required to interact with the device during use, and does not require fingerstick calibration.
- **Patients can use their smartphone to scan new sensors.**
Users with Android phones with RFID or NFC technology are often able to scan modern CGM sensors directly with their phones instead of using the dedicated reader, allowing the creation of large databases of CGM data. This data may be integrated with inputs from other devices or mHealth apps to provide context for physicians. Additionally, the collection of CGM data will contribute to the generation of a digital ecosystem surrounding diabetes that may be used to improve understanding of the disease and potentially design strategies for personalized diabetes therapy and prevention.
- **Companies aim to expand the market for CGM sensors.**
CGM sensors have typically been aimed towards type 1 diabetics, however they represent only 5–10% of diabetics (Healthline, 2017). Several companies are therefore developing CGMs for type 2 diabetics as well as targeting the pre-diabetic market and potential non-diabetics taking part in wellness or fitness programs.

Medtronic positions itself to minimize the impact of diabetes on patients

- **Medtronic announced a partnership with Fitbit in 2016 to integrate activity data with data from Medtronic's iPro2 continuous glucose monitoring system.**

Using this feature, users are able to see the connection between exercise and glucose levels, which represents a critical element to proper diabetes management. Although only available for one device so far, the companies plan to offer more solutions in the future. Both consumers and their physicians will be able to see the correlation between physical activity and glucose levels before and after eating, which can empower patients and enable physicians to devise more personalized management strategies.

- **As data collection continues, Medtronic move closer to automated insulin delivery.**

In 2017, Medtronic launched the MiniMed 670G, the first hybrid closed loop system for type 1 diabetics. It is the only approved insulin pump that enables automated delivery of basal insulin to maintain blood sugar levels throughout the day and night. This product begins a new era of diabetes management in which glucose management can be almost entirely automated, which Medtronic is striving towards. The MiniMed currently requires user inputs when performing non-baseline activities such as exercise and upon eating, and GlobalData expects Medtronic to be using the data collected from the device to improve their algorithms and capabilities in the coming years.

In a new age of patient engagement, mobile apps aim to empower diabetes patients

- **Wrist-worn wearables may provide an easier method of diabetes management.**

An early study on the merits of self-management applications on smartwatches found that wrist-worn wearables made the recording of activity levels, glucose levels and other health measurement inputs easier for patients (Årsand et al., 2015). Since publication, diabetes management apps have become abundant on Apple, Android, and smartwatch platforms, typically including tracking and visualization of blood glucose, insulin, food, and exercise.

- **Apps can connect remote patients with physicians.**

Livongo is a care management platform for diabetes being used by Alaska's largest primary care group, to enable patients to access clinician support and guidance between visits and providing clinicians real-time access to patient data (Wicklund, 2017). This care model provides support for remote patients without requiring travel, however reimbursement remains a barrier to adoption.

“Where these [wearable] devices can really make an impact is in chronic diseases. You see it starting with diabetes, like Medtronic and Fitbit’s partnership... More and more patients are going to be using smartwatches and apps to manage chronic diseases.”
- Key Opinion Leader

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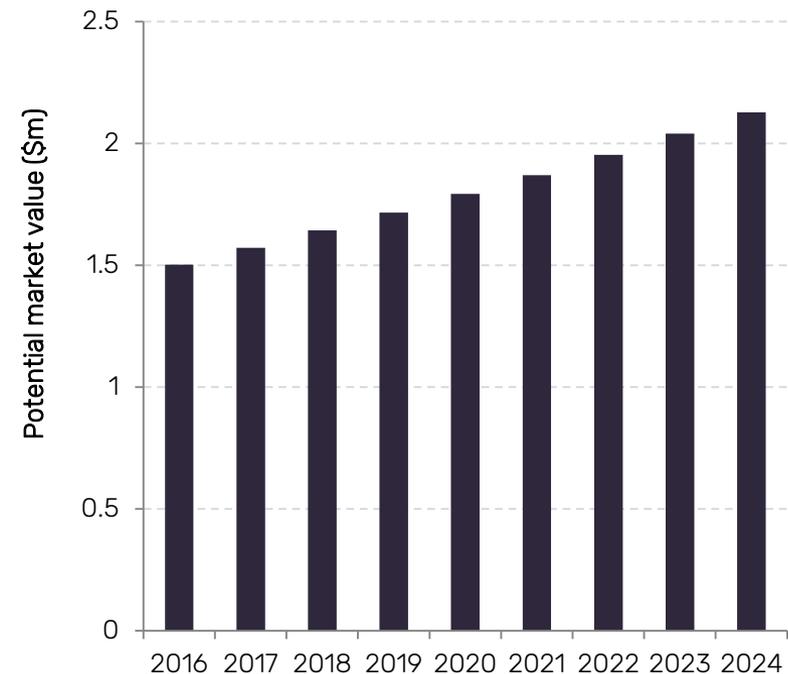
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Neurology wearable devices are numerous and varied, from pain relief to diagnostics

- With an aging population, an increasing proportion of patients suffer from neurological diseases.

In 2017, approximately a third of the total population suffer from neurological diseases such as Alzheimer's, multiple sclerosis, migraines, and epilepsy (OHSU, 2017). This population is expected to increase smartphone and wearable usage in the next 5–10 years, providing a large potential market for device and app development. As neurological diseases are highly varied, the devices range from wearable pain relief to clinical research and observation of degenerative diseases such as Alzheimer's via mobile apps.

Neurology mHealth app Potential Market Size



Apple's ResearchKit enables researchers to enroll patients and conduct studies via iPhones, while the CareKit provides a software framework for apps to manage disease

- **Researchers are able to develop apps to reach large cohorts of patients for studies.**
Current measures of neurological health are often based on sporadic visits to clinicians, typically every 4–6 months for a Parkinson's patient. One app, mPower, aimed to establish baseline variability in real-world scenarios for patients with Parkinson's, and was able to recruit 9,520 participants to the study (Bot et al., 2016). Although consistent use of the app was rare, this demonstrates the powerful role mobile apps could play in clinical trials and studies.
- **People with epilepsy track symptoms and notify carers of a seizure using Apple Watch.**
Researchers are using the Apple Watch to track the onset and duration of seizures in real time, creating a correlation between episode history and medication, in an effort to eventually predict when seizures may occur. Participants launch the EpiWatch app when they sense an impending seizure, which triggers the accelerometer and heart rate sensors and automatically sends an alert to a designated family member or caregiver. These applications enable researchers to utilize the vast power of big data in healthcare to increase our understanding of neurological disease, which GlobalData expects to play a large role in future clinical research.

Injuries caused by falls among seniors are a major challenge in US healthcare

- **Wearable devices provide an opportunity for fall detection systems for seniors.**
Over 800,000 patients per year are hospitalized because of a fall injury in the US (CDC, 2015). As swift medical response after a fall is key to reducing morbidity of falls, research into automatic and reliable fall detection systems has increased in the last decade. With rates of smartphone ownership increasing, some developers have focused on utilizing the accelerometer capabilities within smartphones to detect falls, while others have opted for stand-alone wearables such as a patch or bracelet.
- **Accuracy of data from fall trackers is disputed.**
While the potential benefits of fall trackers are plain, key opinion leaders stress the importance of providing accurate data. In a small study of community-dwelling older adults, a cohort of residents recorded a total of 84 alarms over a 4 month period, 83 of which were false alarms, which may dampen market growth (Chaudhuri et al., 2015).
- **Smartwatches provide existing technology for development of fall tracker applications.**
Commercial smartwatches integrate accelerometers, potentially enabling them to act as fall tracking devices. While the specificity of smartphones in detecting falls is low, the combination of smartphone and smartwatch can increase the specificity, potentially enabling developers to overcome this initial barrier (Casilari and Oviedo-Jiménez, 2015).

While pain relief traditionally relies on medication, companies are using wearables to apply non-pharmaceutical therapies outside clinics

- **New devices are coming to market aimed at reducing dependence on pharmaceuticals.**

Wearable products providing short- and long-term pain relief are becoming increasingly common. In particular, transcutaneous electrical nerve stimulator (TENS) technology has been utilized by some companies in wearable pain relief devices, such as Quell. Quell comprises an electrode attached to a band that is placed around the calf, which stimulates the nerves to provide pain relief. As competition between pain relief devices increases, GlobalData expects greater emphasis will be placed on clinical trial data, alongside technology improvements.

- **Wearables for pain relief will need to appeal to physicians as well as consumers.**

Pain relief technology has a history of promising more than is possible, however new wearable technology is attempting to overcome this image. However, devices which are able to sufficiently demonstrate their clinical value are expected to gain significant market share in the next five years. Reliance on pharmaceutical pain relief, particularly opioids, is a well-publicised issue in the US, so key opinion leaders expect companies that can provide a clinical alternative for physicians to thrive.

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Although many different types of healthcare apps have been developed, the most popular focus on empowering consumers to take control of their health

- **Calorie counters and activity trackers are consistently some of the most downloaded healthcare apps in the US.**

These applications bridge the gap between consumer products and clinically useful data. Apps that integrate tracking of calorie intake, exercise levels, weight, blood pressure, and others are becoming more popular as consumers become more focused on maintaining their health. Physicians have stated that the most useful information clinically is often simply weight and blood pressure recorded on a regular basis. As a result, GlobalData expects these tracking applications will maintain their popularity with consumers, and will drive more physicians to use data from wearable devices and apps.

“People want to be more informed about their health... society is getting more aware of the concept of health being healthy and not just the absence of disease. I can see wearables and apps playing a role there already. I see wearables being a health follow-up tool rather than a disease follow-up tool.”
- Key Opinion Leader

More patients are becoming aware of the possibility of chronic disease management using tailored mHealth applications

- **mHealth applications are able to ease the burden for patients with chronic diseases.** Research into use of a wearable device and app in combination with medication for patients with osteoarthritis in their knees saw a significant difference between the increased number of steps per day and reduction in pain during a six-minute walking test (Skrepnik et al., 2017). Compliance rates for the mHealth app and wearable were very high, evidenced by the large proportion of patients continuing to use the technology after the 90-day study period ended. This and similar studies demonstrate the value of wearable devices and mobile applications not only for patient monitoring, but in management of chronic conditions and improved patient outcomes.
- **Healthcare applications can have simple interventions.** In the US, 7.6% of adults currently have asthma. Pollen is a common trigger for people with asthma, with high pollen count linked to an increase in hospital admissions (Jariwala et al., 2013). For these patients, apps can aid in managing triggers and medication. One example is Propeller, offering a “Daily Asthma Forecast” to alert users to potential asthma triggers in addition to tracking medication, and sends alerts to a designated physician or family member when a user’s symptoms worsen.

Wearable devices have the ability to increase granularity of clinical trial data

- **Clinical trials currently rely on isolated snapshots of a patient's health throughout the trial period.**

Use of wearable devices provides researchers with real-world, continuous measurements as trial subjects follow their daily routines. Not all trials will benefit from the data provided by current sensors, however for some trials heart rate tracking would provide key insights, for example if a new drug may potentially affect cardiovascular function.

- **The FDA is increasing focus on personalized healthcare in products and clinical trials.**

As trials become more patient-centric, GlobalData expects use of wearable technologies for remote patient monitoring to become more common in clinical trials. The ability to collect more data on individual subjects will inevitably increase use of wearables as non-invasive sensor technology improves.

“Growth in these [wearable] devices will be at least in part from their use in clinical trials. Clearly at some point the regulatory agencies will be able assess the efficacy of all these new drugs and interventions not just by how well somebody can walk after six months but using data gathered from the whole trial period.”

- Key Opinion Leader

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Clinical utility remains a key unmet need for wearable devices

- **Current data is not clinically actionable.**

Although there have been news stories about smartwatches saving lives or predicting a diagnosis, these are exceptional cases. For the vast majority of the population, heart rate data and sleep trackers provide little to no clinical value for physicians. Wearables need to provide actionable data before clinicians begin to advise their use. Two key parameters highlighted by key opinion leaders are weight and blood pressure, for which some companies are marketing connected devices.
- **Medicine compliance tracking would be valuable to physicians.**

Although apps exist for tracking medicines, they are not widespread and are often not used. Incorporating notifications into wearables and facilitating tracking of patient compliance would be particularly useful as non-compliance of patients is currently a major issue in healthcare.
- **Transcutaneous sensors would be capable of more sensitive measurements of a broader range of biological molecules than watches.**

While minimally invasive sensors are becoming more common for diabetes monitoring, transcutaneous sensors for different biological molecules will be a major step forward for wearable technologies in diagnosis and management of chronic disease, and would likely result in increased adoption.

Physicians are looking for actionable data from wearables

“All of these data become more attractive if there is actionable intervention that is linked to it. This is not to dis[respect] the data, because there are two applications; one is to understand the physiology and to research how many patients have certain symptoms, but that is just for research; and two, using these data to assess the efficacy of therapy. None of these things are ready for clinical use today.”
- Key Opinion Leader

“If they bring this data into clinic I don’t have any additional use for it outside of talking to the patient about their symptoms. Maybe if it could track medication compliance or something similar, but at the moment with just heart rate there’s not a lot of use.”
- Key Opinion Leader

“If there are transcutaneous sensors that can figure out your K level or glucose level and is automatically sent to your watch, that would definitely hold promise for clinical treatment, but that’s not what today’s watches are giving you... Even if they did, we have blood tests today, and we can get glucose levels and K levels so it’s not like we don’t have a solution today, so the solution you’re coming up with to the problem is ease, not that we don’t currently get the data.”
- Key Opinion Leader

Reliable data must be provided by wearables before physicians are able to use it clinically

- **Physicians require guidance on how to use data collected from wearable devices.**

Currently, most wearables are not classified as medical devices, and thus are not regulated as rigorously as physicians are accustomed to. As a result, many physicians will be reluctant to use data from wearable devices due to the lack of data validation and guidance from regulators as to how to use this information. More input from regulators is required to overcome this hurdle to using this data.

- **Few reliable sensors are located off the wrist.**

While there are some products available, the majority of wearable devices sold are wrist-worn. As miniaturization of technology continues, manufacturers will be able to produce smaller wearable devices that can connect to a smartphone or computer to track and monitor patients.

“We have approached the FDA several times for their perspective... if you can actually get a lot of information on a day-to-day basis should we accept it? I don’t think we’re there, I think the world is moving in that direction but [wearables] need a lot of validation and understanding of what you are getting from these data.”

- Key Opinion Leader

Wearable devices can not yet interact directly

- **Data interconnectivity is vital to enable widespread use of data from wearable devices.**
Currently, there is no digital standard for interoperability between wearable devices. As a result, it is difficult to include data collected from wearable devices into existing patient notes, particularly as many device manufacturers prefer to hold the data in proprietary apps and cloud services. This poses a problem for the uptake of wearable devices in a healthcare setting, as physicians will not be able to utilize the data collected. In Europe, there has been pressure from some governments, for example in the Netherlands, for device manufacturers to conform to data sharing standards. This is a trend GlobalData expects to continue as wearable devices become more widely adopted for healthcare.

“Healthcare providers can’t make the most of data from wearable devices until they can connect with existing healthcare infrastructure. It needs to be easy to include data from wearables into an electronic medical record.”

- Key Opinion Leader

“Many device makers now offer connectivity but when you look under the hood it is a proprietary system. They offer an app, then they offer a private cloud service. Everybody wants to keep their customers within their own walled garden which creates a problem when the healthcare system wants to access that data.”

-Key Opinion Leader

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Pipeline products seeking FDA approval

Many wearable pipeline products focus on improved sensors for heart rate monitoring to enable detection and monitoring of arrhythmia, in addition to other vital signs. Below is a selection of key pipeline wearable devices currently being tracked by GlobalData. This list includes only those applying for FDA approval prior to launch.

Product Name	Company	Stage	Estimated launch date	Application
BioDatix WristBand	HealthDatix	Clinical	January, 2019	Remote Patient Monitoring
BioStampMD	MC10 Inc	Clinical	January, 2019	Patient Monitoring
BuddyWOTCH	Aseptika Ltd	Clinical	January, 2020	Remote Patient Monitoring of Chronic Obstructive Pulmonary Disease
Cor/log BAN BT	CGS Sensors	Clinical	January, 2021	Vital Signs Monitoring
Cortrium C3 Device	Cortrium ApS	In Approval Process	June, 2018	Vital Signs Monitoring
eMotion Fetal Activity Monitor	TinyKicks Inc	In Approval Process	June, 2018	Fetal Activity Monitoring

Product Name	Company	Stage	Estimated launch date	Application
Everion	Biovotion AG	In Approval Process	June, 2018	Vital Signs Monitoring
Google Wristband	Verily Life Sciences LLC	Clinical	August, 2019	Vital Signs Monitoring
HDWear	BioSensics LLC	Clinical	October, 2020	Remote Patient Monitoring for Huntington's Disease
iBeat Heart – monitoring smartwatch	iBeat Inc	In Approval Process	June, 2018	Heart Rate Monitoring; Remote Patient Monitoring
ID-Cap System	etectRx Inc	Clinical	January, 2020	Medication Adherence Monitoring
MICROS Physiological Sensor	Vivonics, Inc.	Clinical	January, 2019	Patient Monitoring
Mobile Wireless Fetal HRV Monitor	Biotricity Medical Inc.	Clinical	July, 2020	Fetal Heart Rate Monitoring
PAMSys	BioSensics LLC	Clinical	July, 2019	Remote Patient Monitoring
Reveal	Awake Labs Inc	In Approval Process	June, 2018	Patient Monitoring for Anxiety
Skin-Like Device	University of Illinois	Clinical	July, 2018	Remote Patient Monitoring

Product Name	Company	Stage	Estimated launch date	Application
Sleepi-Band	North Carolina State University	Clinical	January, 2019	Vital Signs Monitoring; Diagnosis Of Sleep Disorders
Upper-Limb Frailty Meter	BioSensics LLC	Clinical	May, 2019	Remote Patient Monitoring for Trauma
Vitaliti Wearable Health Monitor	Cloud DX Inc.	Clinical	January, 2020	Patient Monitoring for Huntington's Disease
Wearable Heart Rate Monitoring Device	Seoul National University Hospital	Clinical	December, 2019	Remote Patient Monitoring; Heart Rate Monitoring
Wearable Sensor Patch - Parkinson's Disease	MC10 Inc	Clinical	January, 2021	Remote Patient Monitoring for Parkinson's Disease
Wearable Sweat Sensor	University of California Berkeley	Clinical	February, 2019	Remote Patient Monitoring

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The FDA currently does not classify most wearable devices as medical devices

- **The Philips Health Watch is the only smartwatch to be classified as a medical device**
Although companies are beginning to integrate apps designed for healthcare, the smartwatches themselves are not regulated as medical. Manufacturers are beginning to move towards functioning as a medical device, such as Apple seeking to detect atrial fibrillation. As this is a diagnosis, it will require some form of FDA regulation.
- **The FDA clarified the criteria for medical software in the 21st Century Cures Act, enacted in 2016 (Sec. 3060 - Clarifying medical software regulation)**
In terms of consumer products, software that is for “maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease condition” is not considered a medical device. Similarly, software for administrative support of healthcare, viewing electronic medical records, storing test results, or other non-clinical functions are not considered to be medical devices.
- **Medical apps will be regulated using a tailored risk-based approach**
Apps that are “intended to be used as an accessory to a regulated medical device, or transform a mobile platform into a regulated medical device” will be regulated in this way. Iterative changes such as app updates will not require re-evaluation.

THE FDA IS SEEKING A NEW APPROACH TO DIGITAL HEALTH PRODUCT OVERSIGHT

Mobile Health Apps Interactive Tool

The Federal Trade Commission has created an online tool for medical app developers to aid understanding of relevant laws and regulations. The Mobile Health Apps Interactive Tool asks developers a series of questions about the nature of the application, including its function, the data it collects, and the service it provides to consumers. It uses this data to guide the developer towards detailed information about federal laws that may apply to the app.

Pilot Program for New Regulatory Approach

The FDA has begun a pilot program to regulate medical apps by looking first at the developer of the technology before reviewing the product itself. Under this approach, the FDA could “pre-certify” eligible developers deemed to be sufficiently accomplished in areas or organizational excellence. These select developers would be able to market low-risk devices without additional review or with a swifter review process.

Most medical wearable devices are not reimbursed

- **Most wearable devices are aimed at consumers**

As wearable devices are often not classified as medical devices, insurance companies are not offering reimbursement. This will limit growth of the healthcare wearables market, as only those who have the desire to purchase an expensive device will be using the associated medical applications.

- **Insurance companies subsidizing wearables**

Aetna now subsidizes the cost of an Apple Watch for some customers. Although Aetna claims there are no health requirements, other providers are looking to begin tracking customers' health. Life insurance provider Vitality offers an Apple Watch for \$25, provided users stay active. This move has caused concern for many, particularly the impact on disadvantaged people or those with existing medical conditions which may prevent them from exercising as much as others.

“Development hurdles are high, regulatory burdens are high, it’s going to be costly and all the technology developers and drug developers right now are so demoralized because they feel that insurance companies are not going to pay [for the devices].”

- Key Opinion Leader

“There is a huge amount of pushback to insurance companies tracking customers. There is a concern that by doing so you will be discriminating against people with disabilities or social determinants of health, and people who need more help with be disadvantaged further.”

- Key Opinion Leader

The image features a dark blue background with a large, stylized, light blue 'A' shape. The 'A' is composed of thick, rounded lines. In the top left corner, there is a small, solid teal circle. The word 'Appendix' is written in a teal, sans-serif font, positioned to the left of the 'A' shape.

Appendix

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