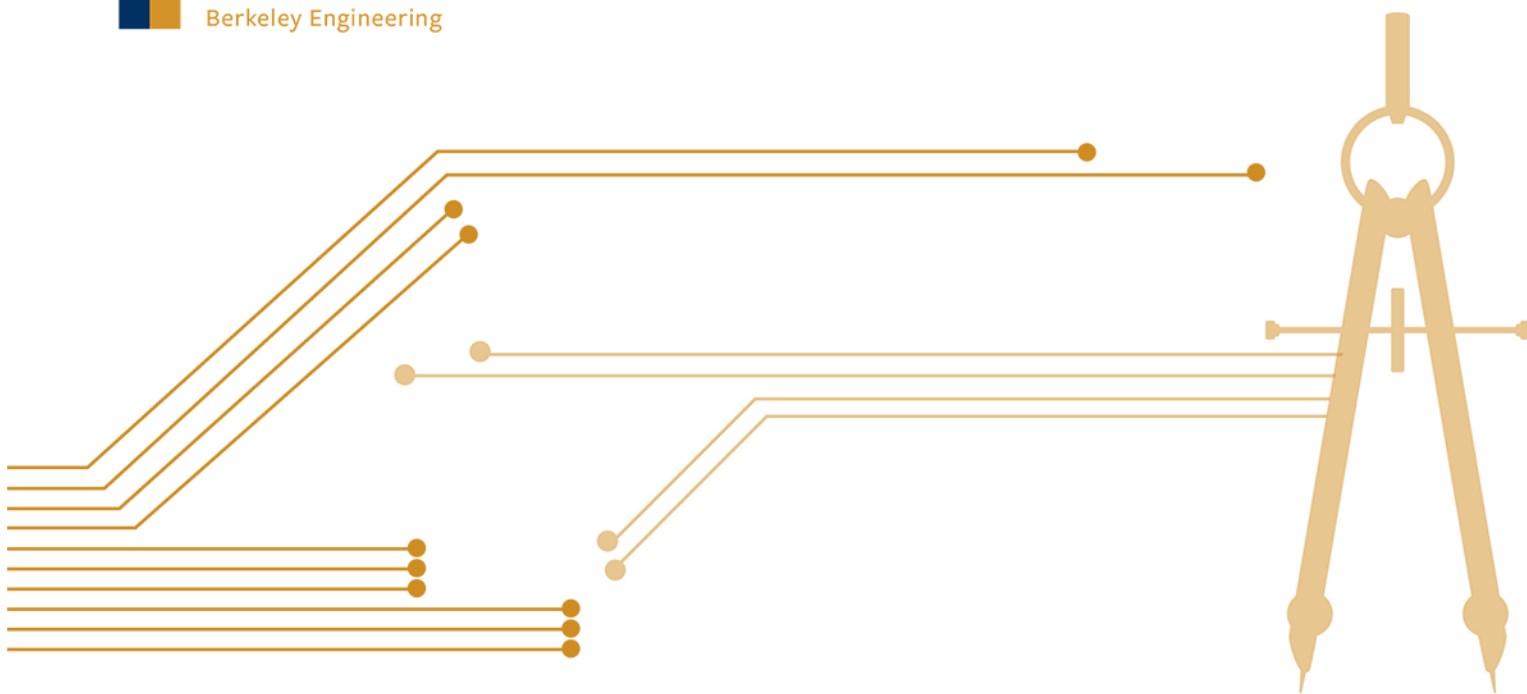




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Executive Summary

Wearable devices are more than just a trendy fashion statement. There is a budding market regarding wearable medical devices that can help users live a longer and healthier life. Companies are starting to recognize the potential commercial viability as they enter this new industry, but there are still challenges and questions to be answered.

The current wearable medical device market remains fairly open with significant development only spearheaded by a handful of companies. There are challenges regarding privacy and regulations that will not be easy to overcome. Companies handle each with different philosophies, which could ultimately impact user trust and adoption.

The present state shows that the market is focused on the initial stage of building the ecosystem. The future of the industry relies on data management and the integrated services that can be provided to the user.

Overview of Wearable Medical Devices

Target Audience

Death and disease is tragedy that can sneak up suddenly, leaving families devastated. It is little consolation to learn that millions of Americans are at risk of early, preventable deaths for cardiovascular disease. Heart disease and diabetes are two killers that can be easily monitored and regulated if there was more information about the patient. Yearly check-ups provide a limited view into a person's condition. Imagine a world where the patient and doctor had daily information available to analyze.

The everyday use case for the general population is providing casual information such as step counters and sleep trackers. This is seen as a platform to launch into the next sector. This second focus is geared towards patient monitoring, providing a deeper understanding of how the body works every moment. There is potential for a world where medical diagnosis can be informed by several days of data.

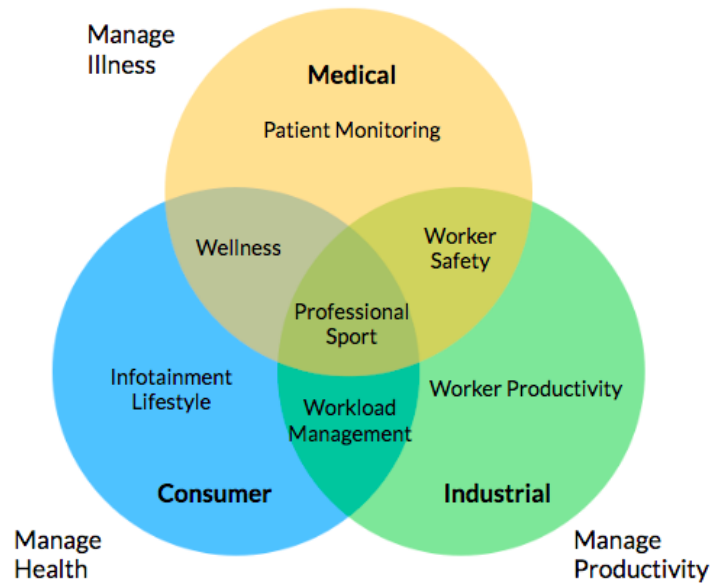


Figure 1: A diagram of the different use cases and potential overlap.

Type of Devices

Currently the market of wearable devices can be broken up into 3 categories:

- Consumer devices: help manage health, but mainly serve as infotainment.
- Medical devices: help monitor patient's health post-op and / or manage illnesses or existing conditions.
- Industrial devices: help manage worker productivity.

The current industry has a focus on the intersection of consumer and medical devices that ultimately focus on wellness.

There is a large selection of different sensory devices available. They are designed for every part of the body such as head, chest, arm, wrist, finger, limbs, and ankles. Some devices are being incorporated into clothing and other clothing accessories, like belts.



Figure 2: Examples of available wearable devices

Market Analysis

Competition in this segment is strong and healthy. There are well-established consumer electronic companies, such as Apple, Xiaomi, and Samsung, with a large number of startups, such as Fitbit and Withings. Some companies are focusing on specialized single function devices, while others are working on multi-sensory devices.

Market Trend

The growth for wearable devices is an increasing trend. Current projection shows that the number of wearable devices will increase from 122 million units in 2018 to 225 million units in 2022. The market for fitness and wellness devices is expected to grow to \$27 billion by 2022.

North America wearable technology market by application, 2012 - 2022 (USD Billion)

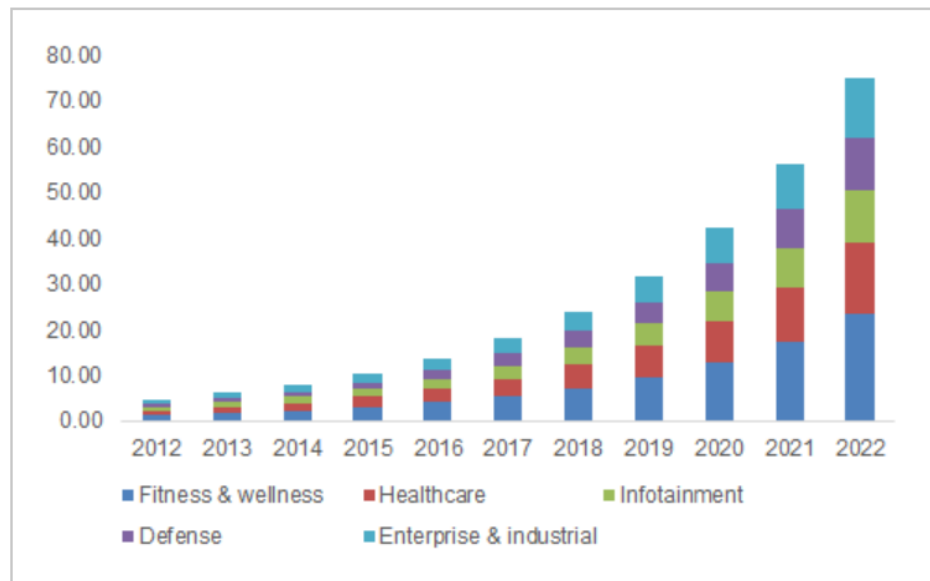


Figure 3: Project market growth for different areas of wearable technology from Reference 1

Looking closely into the trend of the type of devices, smart watches show the biggest projected growth with fitness trackers showing the biggest decline. Smart watches are forecasted to grow by 67% over the next four years. In turn, fitness trackers are forecasted to decline by 53% during the same four years. Although, currently not an established market, ear-wear devices are expected to grow functionality beyond audio. New features are targeted to encompass fitness tracking, coaching, real-time translation, and a smart assistant.

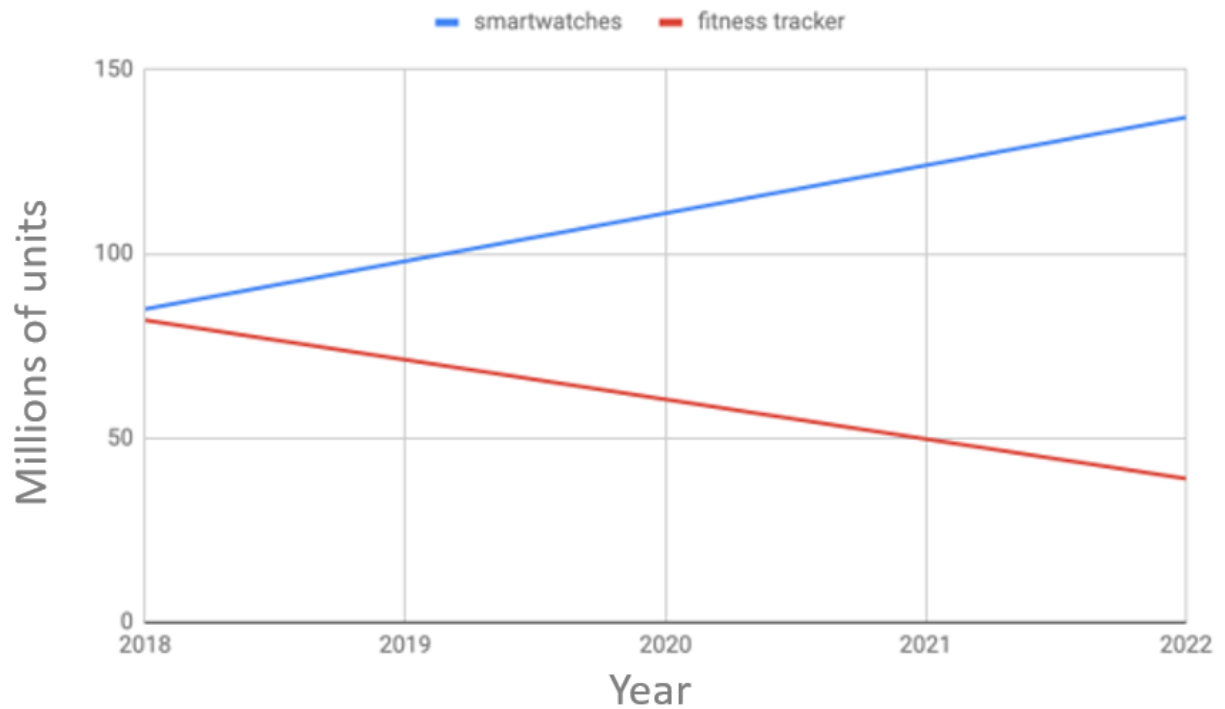


Figure 4: Graph generated from Reference 2

Adoption Trend

The market has a number of innovative wearable devices for sale to the everyday consumer. Growth for smart watches is expected to continue to trend positively, but the current lifecycle position is estimated to be at the tail end of the early adoption phase.

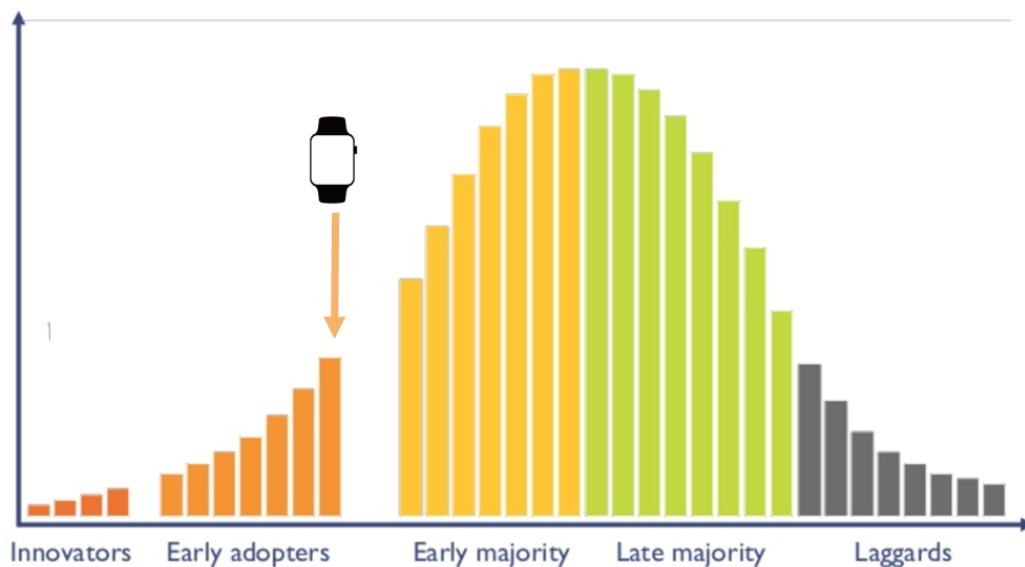


Figure 5: Technology lifecycle curve and the estimated location of smart watches

The technology is not considered in early majority phase due to the steep price that can dissuade most customers. The Apple Watch Series 4 starts at around \$399 for the low end model, which does include the electrical and optical heart sensor. The FitBit Inspire is available at \$69.95, but does not provide the same functionality. The FitBit Inspire only acts as a step counter, with no available application suite like the Apple Watch. The Apple Watch also does hold other advantages such as partnerships with regulatory bodies.

A potential model to penetrate a larger user base is partnering with insurance companies. Providing a subsidized device to users would allow high risk patients to adopt smart devices. As a result, the impact on monitoring conditions such as heart diseases and diabetes would lead to improved quality of life.

Merger and Acquisition Trends

In 2018, there were a record breaking 54 acquisitions in the field of wearable medical devices. Of those 54 acquisitions, 13 of them amounting to \$7.6 billion. A small dip can be observed in 2017. The overall increasing trend (Figure 4) is expected to grow as the market space expands to more traditional healthcare companies while new applications are developed.

These acquisitions can be grouped into three segments:

- **Devices** (~\$3.6B) is the largest segment by dollar amount. This segment focuses on hardware development for collecting the data. Few examples are connected glucometers, automated insulin delivery wearables, and connected respiratory devices.

- **Data** (~\$2.2B) is the next largest segment. This segment is related to methods for communicating collected data to users and health institutions. Examples are patient communications applications, Electronic Health Record (EHR) software, hospital notification applications, online virtual care platforms, and telemedicine platforms.
- **Analytics** (~\$1.2B) is the smallest segment, however not significantly smaller. This group is related to utilizing the collected data such as algorithms for diabetes prediction, clinical decision support software, and cloud-based artificial intelligence (AI) and data analysis.

Based on these trends and the content of acquisitions, it can be observed that the industry is at the phase of building out the ecosystem. Present day corporations are investing heavily on the hardware development with less attention on software and algorithms. This trend is expected to flip as hardware devices mature and application development increases.

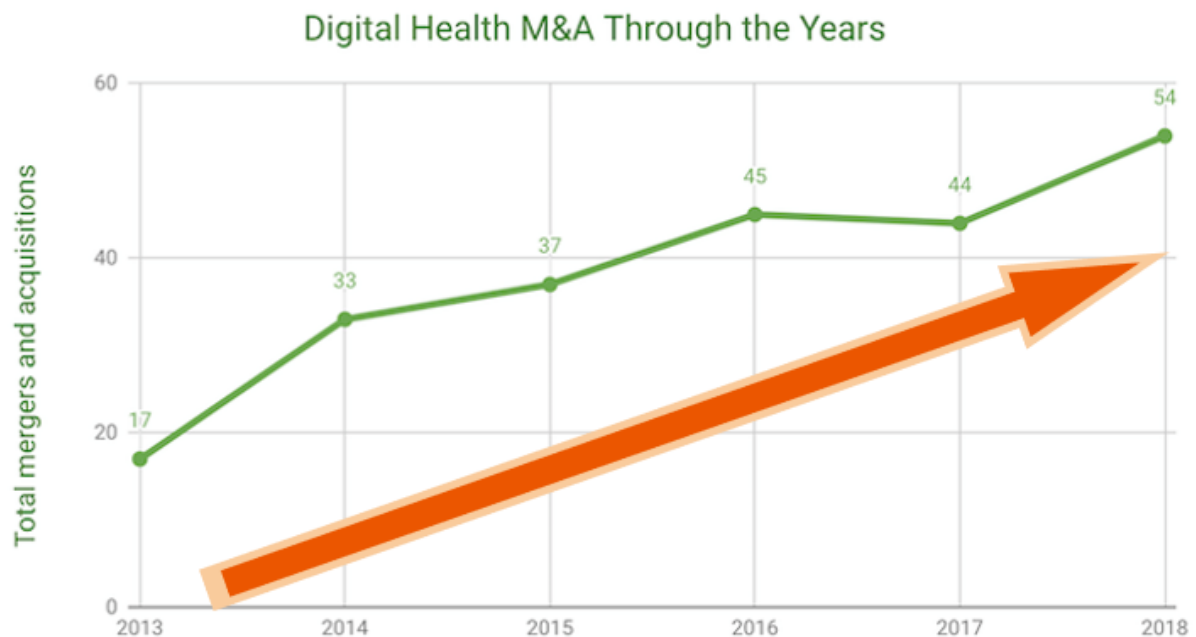


Figure 6: Trend of acquisitions and mergers from 2013 to 2018 for digital health industry from Reference 3

Constructing an Ecosystem

David Benoit, co-founder of Wearsafe, stated that “In 10-15 years, wearables will be less about the hardware and more about the platform on the device. The current adoption rate of wearables is growing, but most consumers lose interest within 30 days. The wearables that will win market will support meaningful services”.

Data Aggregation

Wearable health devices are now part of the Internet of Things (IoT) revolution. These are devices that are connectable to communication infrastructures, thus making it easier to aggregate their data. This data can then be used to develop specific profiles on groups of patients. This allows medical industry professionals to identify common characteristics that may aid in the prediction and effective treatment of a particular disease. Naturally, data aggregation in healthcare can be used for disease prevention purposes. The amount of data wearable devices can open up unique opportunities in the data services space.

Data Services

There is an estimate of over 2.3 trillion gigabytes (GB) of IoT-based data that will be produced daily by 2020 [4]. This will reach an accumulation of 847 zettabytes (ZB) by 2021 [5]. As a result, a slew of startups, aided by robust funding, have popped up to make sense of this collected information [6]. This is not a fleeting startup trend as big companies are also making significant moves in the data analysis direction.

- **Microsoft** launched a new healthcare division to use AI software in the health market [7]
- **Google** acquired DeepMind - AI platform to mine medical records for better/faster health services [8]
- **Amazon** created a healthcare group known as 1492, and it has been aggressively recruiting top talent in the medical healthcare business [9]

These companies are providing data services that facilitate:

- Remote doctors - monitor patients remotely and in real-time
- Smart insurance plans
- AI systems for early disease detection
- AI systems to increase accuracy and speed of diagnostics

All this tremendous amounts of data will facilitate efficient data aggregation and relevant data services must live somewhere.

Cloud Services

The move to cloud services for healthcare is inevitable. Major companies such as Google, Microsoft, and Amazon already provide healthcare specific cloud products driven by Google Cloud, Microsoft Azure, and AWS. These cloud services allow these large stores of information to be accessed remotely and quickly. This ease of access has allowed data service companies to provide relevant healthcare analytics for benefit patient health.

This wearable healthcare revolution has not been fully realized. There are many new developments and challenges ahead.

Challenges

Privacy

Privacy is often a major concern when it comes to wearable medical devices, as they operate on healthcare data that is always considered protected and highly sensitive. Who owns the data? Where and how is it stored? Who will it be shared with and will that be transparent to the owner of the device? These are just some of the questions that the industry needs to have an answer for.

In the current market, Apple can be considered a leader in the privacy policy. Their motto of “what happens on your iPhone, stays on your iPhone” has been proven to be true many times over with the features of the device that emphasize the privacy aspect. That extends to the Apple Watch and the other health related applications on the iPhone. The privacy policy states:

- If customers upload their medical records to iCloud, data is encrypted and protected.
- The personal data is never shared without the user’s permission. [10]

However, not all players in the industry hold themselves to the same standard. An example is Xiaomi who is also one of the world top leaders in the smartphone industry. Xiaomi is also one of the top manufacturers of the wearable fitness trackers. Their privacy policy allows them:

- Collect user’s personal information, financial details and more.
- Share user’s personal Information with a third party without user’s further consent. [10]

The positive news is that there is a global trend to mitigate concerns around security and data access of health information through government policies and new legislation. For example:

- **In the USA**, there is new legislation in some states that hold third parties accountable to the same standards of privacy and confidentiality as where the data originated. [11]
- **In the European Union**, General Data Protection Regulation (GDPR) went into effect and expanded the list of sensitive personal information to include genetic and biometric data. It also made user’s consent required for all data collection and processing. [12]

Regulations

On the regulations front, there is a lot of activity and change. The scope of regulated medical devices is expanding to include the new wearable technologies. This includes providing updated classification categories and the process for acquiring those.

- **In the USA**, Food & Drug Administration (FDA) recently overhauled the medical device review process to that might enable new devices to reach the market much sooner. [13]
- **In the European Union**, there were major updates done to the Medical Devices Regulation (MDR) classification rules & requirements for medical device software.

Among the current players in the market, Apple paves the way in the regulated environment too. The Apple Watch is the first and only among the new generation of compact wearable medical devices that has successfully got a clearance from the FDA. Apple Watch ECG application was granted a De Novo classification [14], which is a category designated for devices unlike anything else on the market. This potentially makes it easier for other companies in the industry to get a classification for their own device, as FDA is now more familiar with how new technologies operate and develop. At the same time, it puts a higher bar for all devices on the market, as they would need to match up with the performance and clinical evidence that Apple has provided for the electrocardiogram (ECG) application.

Looking at What's Next

Future Technology Trends

Before we dive into predictions about the future, here are some of the new technologies in development today. There are three emerging trends of wearable devices that will aid in growth of this market.

There has been an increased focus on the development of non-invasive devices compared to the previous generations of monitoring. This seamless integration of devices to our daily lives will be key adoption of a wide range of users. Existing glucometers require a blood draw to measure glucose levels. Non-invasive methods are currently in development by companies such as GlucoWise that uses devices that emit low power radio waves to monitor glucose levels without needing to take blood samples. Another example is a device by Integrity in which the device uses a combination of ultrasonic, electromagnetic, and thermal data to determine the glucose level. Google has worked on developing a smart contact lens that can monitor glucose levels through tears. This project was halted in Nov 2018, but this indicates the direction of innovation. We expect to see research and development for non-invasive methods as current users are not satisfied of inconveniences caused by methods available in the market today.

Another trend is for devices to have capabilities beyond monitoring. As mentioned, market share of wearables that monitor data are diminishing compared with smart devices. In the future, these devices will perform diagnostics based on the data while also executing other tasks. These devices will monitor real time biology and could be

capable of calling for medical assistance. These devices can also be connected to in-body intranet devices that deliver the appropriate dose of treatment drugs without needing doctor intervention.

One last trend worth mentioning is in the area of invasive products. Development of nanotechnology enable ways of embedding sensors under the skin. This method is invasive, but allows continuous monitoring of the body with heightened accuracy.

Advancement in IoT technology will enable future health systems to establish connections and come up with new standard solutions for diverse medical solutions.

Leading the Industry

The biggest concern for consumers to adopt wearable medical device is personal privacy and data protection. The market will be led by companies with best privacy protection of medical records and protection of data collection. This is supplemental to software features and hardware functionalities. Gene Munster, managing director of Loup Ventures, said that “if the future of healthcare is more proactive and progress toward wearable devices, then the questions is which companies are best positioned. I think the privacy angle, its perspective on privacy, give Apple a big head start” [15].

Tim Cook, Apple’s CEO, mentioned in an interview that Apple’s biggest contribution for mankind may be revolutionizing the world of healthcare. With Apple’s rigid privacy policy and clear vision from CEO, more than 120 hospitals are working with Apple on an EHR system. The latest example is the first introduction of an FDA approved ECG on Apple Watch. Apple recently filed patented versions of AirPods wireless earbuds with healthcare applications aiming to detect stress levels. [16]

Apple is a clearly the market leader of wearable medical devices. Other major tech companies, such as Alphabet, Microsoft, and Amazon, have also launched their own healthcare projects.

Alphabet is heavily invested in developing future applications that run on wearable devices. They filed 186 patents related to medical and healthcare between 2013 and 2017. Alphabet’s research organization, Verily Life Science, raised \$1 billion in January of 2019 from private equity firm Silver Lake and others investors. Its project baseline has partnerships with Stanford and Duke to identify health risks and better understand early symptoms of various diseases. [17] Verily has also worked with healthcare partners to bring data driven approaches to battling opioid addiction. Its smart watch aims to collect neurological data that could detect the onset of Parkinson’s disease. [18]

Conclusions

Wearable medical devices can have a real and positive effect on people's health. The industry around these devices will have tremendous growth and opportunities for businesses.

Health wearables with AI and big data are providing an added value to healthcare with a focus on diagnosis, treatment, patient monitoring, and prevention. Big data and wearable devices will allow medical professionals to access detailed and accurate history of the patient's health. This will offer multiple advantages to catching early symptoms and providing effective treatment. The current ecosystem integrating cloud services is being actively developed. There will be a shift towards software services as the hardware innovations stabilize.

Major obstacles in the adoption of these devices still exists due to regulations and privacy concerns. Companies, such as Apple, are providing a path forward by working with government bodies. This cooperation will provide resolution for these concerns.

The advancement in wearable health technology today is amazing compared to just a few years ago. Imagine what advancements in 20-30 years will bring. As Tim Cook of Apple states, "On the healthcare, in particular, and sort of your well-being, this is an area that I believe, if you zoom out into the future, and you look back, and you ask the question, 'What was Apple's greatest contribution to mankind,' it will be about health... And as we've gotten into healthcare more and more through the Watch and through other things that we've created with ResearchKit and CareKit and putting your medical records on the iPhone, this is a huge deal... We are democratizing it. We are taking what has been with the institution and empowering the individual to manage their health. And we're just at the front end of this."

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