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# Wearable Technology in Healthcare

Healthcare

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In 2018, the wearable tech market was worth nearly $23B and is likely to grow to $54B by 2023, according to GlobalData forecasts, growing at a Compound Annual Growth Rate (CAGR) of 19% by 2023. Wearables have been adopted in a wide range of fields; however, they have their greatest potential in healthcare to address spiraling healthcare costs, aging populations, and the burden of chronic disease.

In healthcare, wearable technologies are defined as noninvasive and autonomous devices that capture, analyze, and aggregate physiological data to improve personal health and well-being. Wearable technology has been used almost exclusively for fitness purposes to date, steered by the increasing demand of consumers to monitor their own health. The integration of wearable tech with augmented reality (AR), Big Data, artificial intelligence (AI), and cloud computing solutions, as well as the falling prices of sensors, open-source application programming interfaces (APIs), frameworks, and libraries, is enabling faster and more cost-effective solutions within the Internet of Things (IoT) ecosystem. Recent advances are providing value add for healthcare with a focus on diagnosis, treatment, monitoring and prevention. These advantages are felt through the entire healthcare value chain with benefits including personalization, early diagnosis, remote patient monitoring (RPM), adherence to medication, information libraries, and better decision making, while reducing healthcare costs. Additionally, growing demand and functionality has gathered the attention of insurers and companies in the supply of wearable health technology to consumers and employees for their wide-ranging benefits.

The challenges that wearable technology is facing are broad, from data security, trust issues, and incentivization to regulatory and ethical hurdles. Within the next five to ten years, as connectivity improves and miniaturization enables wearables to become more 'seamless' and integrate more readily into the lives of consumers, their health-related value will be realized.

**The leaders**

This report divides the wearables technology value chain into a variety of application segments. The leaders in each segment are shown below, both for traditional technology and healthcare-specific uses.

| | | |
|---|---|---|
| Hearables | Tech | Apple, Huawei, Google, Sony, Samsung, Bose |
| | Healthcare | Jabra, Nuheara, LifeBeam, Vinci |
| Smartwatches | Tech | Apple, FitBit, Garmin, Samsung, Sony, Xiaomi |
| | Healthcare | AliveCor, Empatica, KinesiaU, Nemaura, Omron, OnePulse, PKvitality, Verily |
| Fitness Trackers | Tech | Fitbit, Garmin, Nike, Samsung, Xiaomi |
| | Healthcare | AliveCor, Brain Sentinel, MisFit, iHealth, Spire Health |
| Eye Wear | Tech | Google, Microsoft, Samsung |
| | Healthcare | Epson, eSight, Immersive Solutions, Vusix, VirZOOM, Medical Realities, Virtamed, OssoVR |
| Body Devices | Tech | Athos, Google, OM Signal, Sensoria |
| | Healthcare | Bonbouton, Hexoskin, Infineon, Neofect, NeuroMetric, Owlet, Sensoria, Siren |
| Skin Patches | Tech | N/A |
| | Healthcare | BioTelemtry, Eccrine Systems, Epicore, Biolinq, Gentag, Medtronic, Nemaura, PKvitality, Theranica, iRhythm |

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## Report type

- Single theme
- Multi-theme
- Sector Scorecard

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This report looks at the state of wearable technology in healthcare on a global scale. The figure below identifies leading companies in wearable technology and categorizes their positions in the landscape. Many wearable technologies are industry-specific, with fitness and sports applications being the most well-established. In the US, Canada, and Europe, Apple and FitBit dominate, with China challenging tech incumbents with less expensive alternatives manufactured by Xiaomi and Huawei.

Wearable technologies with specific health applications are growing in popularity with the approvals of devices deemed medically accurate entering the market. Health-specific products are challenging existing incumbents and traditional players, who previously were limited to fitness and tracking devices. In addition, start-up firms focusing on specific health solutions are amplifying market competition. Large tech companies have responded to this by either launching rival technologies or partnering with the smaller companies in a bid to mark their presence in the market.

Figure 1: Who Are the Leaders and Challengers in the Global Wearable Technology Industry?

| Device Layer | Tech Leaders | | Healthcare Challengers | | |
|---|---|---|---|---|---|
| Hearables | Apple | Huaewi | Vinci | Nuheara | Halo Sport |
| | Bose | Samsung | iRiver On | Mgmanu | Kuaiwear Kuai |
| | Google | Sony | Jabra (GN Group) | LifeBeam | Cosinuss One |
| SmartWatches | Apple | Samsung | AliveCor | Omron | Viatom |
| | Fitbit | Sony | BioBeat | OnePulse | Withings |
| | Garmin | Xiaomi | Empatica | PKVitality | |
| | Huaewi | | KinesiaU | SmartMonitor | |
| | | | Nemaura Medical | Verily Life Sciences | |
| AR Smart Glasses | Google | Microsoft | Epson | Immersive Solutions | Vue |
| | Lenovo | | eSight | Vuzix | Magic Leap |
| VR Smart Glasses | Google | Facebook | Medical Realities | Virtamed | Osso VR |
| | HTC | Samsung | Immersive Touch | StarVR | VirZOOM |
| | Microsoft | | | | |
| Fitness Trackers | Fitbit | Samsung | AliveCor | Jawbone (in development) | Spire Health |
| | Garmin | Xiaomi | Amiigo (Wavelet Health) | MisFit (Azon) | Withings |
| | Nike | | Brain Sentinel | MOCACare | iHealth |
| | | | Everist Health | PAI Health | Actigraph |
| Smart Wear/ Clothing | Athos | Under Armour | Bonbouton (diabetes) | Lifesense Group | Sensoria |
| | Google | | Hexoskin | Neofect | Siren |
| | OM Signal | | Infineon | NeuroMetric | |
| | | | Komodo Tech | Owlet | |
| Skin Patches | | | AliveCor | Gentag | PKVitality |
| | | | Bioliq | Kenzen | Sensonics |
| | | | BioTelemetry | iRhythm | Theranica |
| | | | Eccrine Systems | Medtronic | VivaLNK |
| | | | Epicore | Nemaura | Vista Solutions |
| | | | Eversense | | |

Source: GlobalData

# 3 Industry Trends

Wearables are rapidly evolving into essential tools in the expanding Internet of Things (IoT) landscape, driven by a combination of technological progress on one hand and creation of market demand on the other. Aided by advancements in sensors, active materials, wireless connectivity, and batteries, among others, wearables are increasingly entwining key trends in a wide range of industries. Backed by this, several technology advocates are perceiving wearables as the next frontier of digital transformation—after the smartphone revolution. Although it remains a context of debate whether wearables will demonstrate smartphone-like market influence in the coming years, GlobalData projects that wearable technologies will substantially revolutionize certain application areas in healthcare, as well as logistics, FinTech, insurance, and defense.

The key trends in wearable tech in the healthcare industry over the next two to three years are shown below. GlobalData classifies these themes into three categories: technology, macroeconomic, and regulatory.

## 3.1 Wearable Technology in Healthcare Use Case Trends

Table 1: Wearable Technology in healthcare Use Case Trends

| Trend | What's happening? |
|---|---|
| Inflection Point | In 2018, the wearable technology industry was worth approximately $22.9B, according to an amalgamation of industry estimates. Many forecasters expect this to double to $54B by 2023. To a certain degree, the wearable technology industry is likely to follow Say's Law of Markets, whereby supply creates its own demand. Increasingly capable, connected, and affordable wearable technologies will infiltrate across populations, with more people owning and utilizing wearables for health purposes. In turn, this will spawn new use cases across the healthcare ecosystem from surgery, preoperative & postoperative care, hospital, doctor appointments and referrals to general health and well-being in the predictive medicine sphere. The industry as a whole is expected to grow at a double-digit CAGR until 2023. Connected devices will increase as factory automation accelerates, especially in China, where the prices of sensors will continue to fall, while the availability of open-source APIs, frameworks, and libraries will increase, enabling faster and more cost-effective solutions within the IoT ecosystem.<br>"It's going to be a short matter of time before patients are connecting their wearables to their healthcare data. And whether that happens inside the confines of the healthcare system or whether it happens outside in a way that the patient controls their own data, I think that still remains to be seen. But this notion that...I think the siloing of these different types of data [is] going to go away. Hopefully, in the next, you know, five to 10 years, you're going to see patients' healthcare data from the hospital being merged seamlessly with wearable sensor data and other types of data that the patients are collecting."<br>US Key Opinion Leader |
| Consumer-Led Healthcare | Healthcare is in the midst of a transformation into a patient-centric, consumer-led model from traditional medicine where, when a person seeks medical help, the doctor is the only source of information and makes decisions based on a fragmented medical history or medical records. This method of care seeking and delivery is inefficient and costly. Wearable technologies and sensors generate rich sets of data and enable their use, making patients and wider consumers the point of care, moving away from patients having to go to the "ivory tower" for health decisions. Consumer-led healthcare over the next few years will change patient care pathways, driving the industry to grow and collaborate in new ways, both with patients around their own health and with partners and innovators. Wearables will primarily support people living healthy lives, and then diagnostic and therapeutic abilities will follow, led by the user themselves at the point of care.<br>*"The first step of this digital transformation vehicle, which is our health, is really contributing to making the patient the point of care. Right now, about half of the potential workforce in healthcare, I mean patients, are left out because they are not being invited to the table to contribute with questions and data. They're just being told what to do."*<br>EU Key Opinion Leader |
| Healthcare of the Future | Innovations in technologies, from 3D printers to automation and robots, are revolutionizing healthcare and creating a unified body of tools where data is continuously processed and analyzed. This aggregate data has the potential to be used for preventative medicine, real-time diagnostics, disease monitoring, and therapeutic delivery. The future of healthcare will facilitate more timely and accurate interventions, improving outcomes for patients and the entire healthcare ecosystem. Sources of data will include healthcare networks (hospitals, clinics, and laboratories), technology networks (sensors, monitoring, and IoT devices), and social networks. The US, Europe, and the Middle East are leading the way in terms of "Healthcare of the Future." Dubai launched the Salem Innovation Center, its first fully autonomous AI medical center, in February 2018. Customers are identified using facial recognition, and receive medical tests and screening services from specialized robots; the tests are sent securely to customers through mobile and online channels, which are all integrated with wearable sensors and mobile health. This delivery |

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| | model is a working example highlighting how digitization helps with the reallocation of human resources to address other challenges in the health system.<br>*"Every minute that we save on unnecessary intervention is a minute that the healthcare clinicians can dedicate to other patients, or dedicate to more complex cases."*<br>EU Key Opinion Leader |
| Big Tech and Healthcare | With the recognition that the world is becoming more digitally savvy and that wearable technologies will be an essential component in the future of healthcare, tech players are becoming ever more embedded within healthcare, either through services, products, or combination ventures. Technology advances and acceptance are driving this integration, as increased populations owning connected devices increases, led by developed nations. Combined with leaps forward in AI and machine learning (ML), the market for wearable technologies is becoming more personalized and disease-specific. Tech investment in health is not new, with M&As increasing in value and number year on year, along with size of those involved. Recent examples include Apple's acquisition of Akonia Holographics, an AR smart glasses company, and the buyout of Tueo Health's asthma monitoring startup, both for undisclosed amounts; as well as Microsoft with its Healthcare NExT initiative, which leverages its existing AI capabilities and Azure cloud resources to help healthcare companies store patient data in the cloud with a Healthcare Bot service that will be integrated with Electronic Health Records (EHRs).<br>*"The big tech companies, Amazon, Google, and Apple, Microsoft… they dominate much of the markets in regards to the ecosystem. The software, even the hardware. The Amazon integration into healthcare is pretty obvious… In the hospitals, for example, you see how the statistics are pretty amazing for Amazon taking over the inventory and the distribution and the dealings with any materials in healthcare. Amazon, the inventory, you need X or Y and Amazon automatically delivers X or Y to you. And it's all autopilot. So that, from there to even the consumer side, Amazon, now you have Whole Foods and pharmacies and it's all integrated into prevention, treatment, and rehabilitation."*<br>US Key Opinion Leader<br>*"The kind of vision that technological companies, healthcare companies, and policies in medical should have in mind, is that the goal is not to make patients wear smartwatches all the time. The goal is to make them wear something they don't even realize they are wearing. But when there is something wrong, or about to go wrong, that is even more important, then we know there is a safety net and they will get notified and they will get a chance to live a longer and healthier life."*<br>EU Key Opinion Leader<br>*"Big consumer wearables like Fitbit, Garmin, or Apple, they all will develop applications that seem to look like it's health-related, but when it comes right down to it, they're not really acting like healthcare companies."*<br>US Key Opinion Leader |
| Healthcare IoT | IoT-based medical devices in healthcare creates a center of excellence, which can help caregivers in monitoring their patients remotely, improve healthcare access, reduce costs, save time, and enable early detection of deterioration. Consequently, digitization of medical diagnostic and monitoring processes are focusing on outcome, reduction in risk, and metered usage. In the future, IoT devices are anticipated to be aimed at prevention and wellness management, technology convergence, and value-based healthcare. In light of this, medical device companies are shifting their interest from device/consumable providers to disease/care management organizations. Companies operating in the IoT space include any connected devices; for example, AliveCor's electrocardiogram (ECG) home monitoring along with its platform, application and other accessories, or clinical-grade biometric sensors from MC10 and Senseonics. In addition, companies such as Google and Apple have ushered in new possibilities, thus guiding medical device companies to innovate via deeper ecosystem collaboration, a factor that is becoming increasingly important.<br>*"You cannot penetrate an organization by imposing a model. You have to learn how the organization works, and you have to collaborate with that organization."*<br>EU Key Opinion Leader |
| Culture Of Digital Health | Healthcare is notoriously slow to adapt to change, owing to its risk-averse nature and regulatory complications. It is expected that as the pace of innovation increases, a change in the culture of how digital health is viewed across all involved—public, policymakers, providers, and payers—and importantly healthcare professionals (HCPs), will follow. While this is happening in some markets—the US, distinct areas of Europe, and Scandinavia—many regions are falling behind. At present, there is little to no incentivization in place to motivate physicians and patients to use and understand the technology in practice. For HCPs, this may be heightened by fear of litigation over devices perceived as new and untested. Communicating the benefits of these devices—improvements in quality, efficiency, and patient experience while transforming HCPs' ever-growing workload—is crucial. GlobalData predict that digital change will require an adaptive approach that is reflexive to the changing needs of staff and the projects undertaken by a healthcare system as a whole.<br>Additionally, we are in the midst of moving away from the idea that digital transformation is purely an IT project, to where it is viewed as clinical change. Consequently, there is a lack of knowledge from the HCP side, where understanding digital technologies is not within current teaching or training schemes. In the UK, East Suffolk and North Essex NHS Foundation Trust (ESNEFT) have showcased the power of digital health, realized through the implementation of automation and AI technologies in practice which "make time matter to free up clinical and corporate time." With a recorded savings of over 10,000 hours during the first year of utilizing these digital tools, including intelligent OCR tech, chatbots, and AI elements with the ability to read unstructured data, the impact is being felt. Darren Atkins, CTO ESNEFT, attributes the adoption of digitization to a positive culture of change within the organization, where all staff are trained from basic programming through to implementation of digital tech.<br>*"We have never been trained for digital health. It's a huge system. It's not health IP, it's not health electronic medal records. It's* |

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| | *their health. It's even more. It's even a bigger culture transformation."*<br>EU Key Opinion Leader<br>*"They [physicians] shouldn't provide data that they can't explain. So then patients would feel like they were still in the ivory tower without any help."*<br>EU Key Opinion Leader |
| Value-Based Healthcare Model | Huge amounts of healthcare data from around the world are stored on site, growing at an exponential rate. Until recently, this dataset has remained within the boundaries of healthcare providers and/ or technology companies, rarely integrated across IT systems. Wearables have the ability to change this data paradigm by distributing insights across the value chain with a huge potential to address chronic conditions, which require long-term management with more complex care pathways. As the distribution of data changes over the next 5–10 years, healthcare will be on the right track to becoming value-based. Data generated by connected devices will be crucial for designing better healthcare programs, which ultimately lead to a reduced incidence of chronic diseases, medication usage, and hospitalizations, with a value-based system that is sustainable and cost-efficient. |
| Remote Patient Monitoring | Remote patient monitoring (RPM) refers to the measurement and analysis of a patient's health metrics including vital signs, heart rate, blood glucose, temperature, and medication adherence, which traditionally would require a patient be physically present within a clinical setting or with a healthcare professional. Health and tech are currently moving away from the more dated ideas of wearables as connected blood pressure cuffs or heart rate monitors and toward wearables that are continuously monitoring health in a non-invasive, discreet, and seamless manner, being both convenient and comfortable for the user. As patients and caregivers are given the option to provide care at home, unnecessary visits to healthcare establishments will be reduced, substantiating a decentralized healthcare model, optimizing the allocation of resources in hospitals and clinics.<br>With global populations aging and increased life expectancy battling dwindling finances and resources, a key market for RPM technologies is in the management of chronic disease, which currently accounts for the most spending in healthcare. With the increasing interest from tech companies in the health space and interest in reimbursement of remote patient monitoring technologies, RPM is likely to trigger significant change.<br>*"What health sensors do is that they bring healthcare home or wherever the patient is. It's not done by other technologies, from AI to virtual reality. It's really done by these sensors."*<br>EU Key Opinion Leader<br>*"The most important thing is to liberate people from having to come to hospitals while reducing carbon footprints, so it's to liberate and empower."*<br>EU Key Opinion Leader |
| Interoperability | Wearables are the most ubiquitous IoT devices and are gradually evolving into key input interfaces for IoT applications. The adoption of wearables as a part of IoT ecosystems is largely impacted by issues such as limited compatibility with other devices and "clumsy" user interfaces. The rapidly growing fusion of intelligent devices with medical devices, institutions such as hospitals and pharmacies, and processes calls for effective management of coordinated and complementary operations. Placed at the heart of IoT, wearables promise to meet the aforementioned demands through platform expansion and provision of larger and more diverse quality data sets for clinical decisions. Wearables are gradually witnessing improvement in terms of interoperability, powered by improving tech solutions such as hardware miniaturization and software augmentation.<br>However, healthcare integration remains problematic as existing, archaic IT systems are incompatible with the variety of market devices and data they generate. These systems require a complete overhaul if the pools of health data generated by wearables and other health-related technologies such as genome sequencing are to be integrated into the healthcare paradigm. It is expected that both health providers and tech developers will steer away from systems that are not designed to engage with this data and will transition to more uniform platforms that are compatible. |
| Wellness and Prevention | *"I did bring my genome sequence to my primary healthcare physician, but she almost had a heart attack that there was no way to include that in my medical record, even though she knew it contained tremendously important information about my clinical life and the future of my health and wellbeing. So we are using that information but we just can't include that in the medical records because there is no entity that can integrate that."*<br>EU Key Opinion Leader<br>To date, the largest market for wearables is activity monitors and smartwatches, driven by the sports and fitness segment. As the popularity of the devices surge, more consumers are encouraged to take note of their own health while passive Big Data collection from connected devices (for example, Fitbits) provides a more holistic profile of individual's health. Increasingly, this data enables the establishment of a clinical baseline where deviations accurately predict, and thus prevent, a disease state. Apple's Smartwatch recently received FDA approval for its ability to provide clinical-grade ECG readings, identifying atrial fibrillation (AFib). Additionally, with the release of the Apple Health Record, it is evident that Apple is bulking up its services and products in the healthcare space with its strategy to build a personal health record. Its activities circumvent the traditional reimbursement model demanded by solutions and devices form Big Pharma, placing the consumer and patient at the center of care with a prevention-style model. This population of the "worried well" culture is motivated to learn about health and the future potential of health, while gaining access to information about disease management decisions. Wearables are an essential component within the prevention-based healthcare model, the potential for which has not yet been realized. It is widely expected that the 2020s will see the growth of proactive, predictive, and personalized prevention, whereby intelligent public health measures are generated through wearable connected devices enabling precision medicine and preventative care. |

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| | *"Patients love getting the device, they love wearing it, they love reporting their data. You know, we paired it up with a consumer app as well, it goes on their phone that then can be used to ask them accompanying question, survey questions. And some of the patients are actually really happy to have a way to feedback information to their healthcare team."*<br>US Key Opinion Leader |
| Insurance | The integration of wearables into life insurance promises benefits to insurers and the insured. Wearable data provides granular insights into a client's health condition and lifestyle. This enables insurers to create customized solutions and increase the number and quality of touchpoints with policyholders, while the insured gain health and financial benefit. Wearable Original Equipment Manufacturers (OEMs) are proactively undertaking measures to communicate the advantage of wearable insurance. For example, both UnitedHealthcare and Oscar Health provide fitness trackers to consumers which encourage both the sharing of data and healthier lifestyle habits in exchange for better premiums and perks.<br>The World Insurance Report 2018 states that around 58% of health insurers are in the conceptualization stage when it comes to capturing real-time member data from wearables. The report also reveals that nearly 42% of insurers have recently initiated budgetary allocations to build real-time wearable data capturing capabilities, while only 12% have established infrastructure to collect real-time data. In order to boost consumer confidence and spread awareness, the US firm Aetna encourages members of large employer plans to use Apple Watches through a discount program of up to $200. Similarly, Cigna offers discounts on policy premiums and cash incentives for meeting fitness goals, with the help of health coaching programs including wearables. In terms of enterprise insurance policies, employers are exploring the feasibility of combining cash incentives with wearable use to lower insurance costs and enhance employee productivity with the Greater Dayton Regional Transit Authority yielding $5M in healthcare cost savings through a wearable-based employee wellness program. Wearables are progressively becoming vital tools in the life insurance sector, especially in the wake of peer-to-peer (P2P) insurance programs – where similar policies are targeted at groups of people who share similar lifestyle and profession. However, voluntary participation becoming mandatory raises ethical questions around privacy and equality.<br>*"It really motivates the system to change. When health insurance companies do something, that's going to be a big change, for sure."*<br>EU Key Opinion Leader |
| Accountability | Digital technologies and combined data enable a more holistic EHR, medical studies, clinical experience, and experience constructing a more holistic medical picture at both the micro and macro level. This is changing the distribution of data and responsibility with the patient as the point of care and engaged in medical decisions.<br>*"At some point, it becomes diffused enough that everybody has the responsibility to use it [wearables]. So I would assume that, at some point, though probably not in the near future, it's going to be expected that clinicians are collecting wearable and sensor data from their patients as part of routine care."*<br>US Key Opinion Leader<br>*"Because of this notion of change in the structure of healthcare, we medical professionals can enjoy the benefits. What happens is we don't have to take all the responsibility around the medical decision, which has to be perfect to a patient, for which I have to know all the medical studies and clinical knowledge and experience, which is physically impossible. We as a health team can work on a medical topic instead of me, alone, trying to solve a problem that I cannot solve alone, only in just a few cases."*<br>EU Key Opinion Leader |
| Regulations Hindering Innovation | International regulatory frameworks and standardized assay methods for medical devices (biomaterials and implantable) are based on risk assessment. At present, regulations are complex and the process is notoriously challenging for developers to pass products through the regulatory framework. In a bid to encourage innovation and ensure delivery of more novel, safe, and effective innovative medical devices to patients, local authorities are encouraged to provide clear and appropriate guidance. In turn, more robust and appropriate guidance could provide the reassurance needed to gain investment, often a deterrent for potential sponsors who remain skeptical on the product's return on investment (ROI). According to Medline, over the period of 2010–2018 this began to change, where increased collaboration among stakeholders was overcoming some of the initial hurdles that have historically prevented medical devices reaching consumers and patients. Ultimately, innovative products require more reflexive regulations with assay methods that are customized and suitable to the device in question, thus streamlining regulatory and scientific evaluation.<br>Additionally, regulatory issues are interlaced with the cultures of large tech enterprises that typically focus on market value rather than real clinical need, with a lack of involvement with the wider medical community who can provide critical feedback during development, and with patients themselves as the end consumer. The result has been limited wearables with clinical utility, and consumable wearables limited to data-collecting capabilities.<br>*"Pharma companies are still very nervous about using non-FDA approved devices for collection, it's quite an uphill battle to convince pharma to use non-FDA approved devices for collecting data."*<br>US Key Opinion Leader<br>*"It would be more helpful and beneficial for the company and the end product and its clinical value to get real criticism from medical professionals. But that's hard to receive, very hard to encourage, and very hard to accept if you have something that you believe in very much."*<br>EU Key Opinion Leader<br>*"Regulation in medicine is stultifying… paralyzing."*<br>EU Key Opinion Leader |

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| Clinical Research | As the pharmaceutical industry increasingly looks to validate patient reporting with real world data, it's also looking towards developing novel endpoints for drug discovery during research and development (R&D) and every stage of clinical trial development. Wearables can drive improvements by optimizing innovation and improving the efficiency of R&D with more reliable data, lower costs, and improved effectiveness. Benefits include reducing the time at the clinical site, lessening the burden of trial participation for patients, earlier decision making, faster alerts to non-compliance, improved success rates for trials and enabling them to move from Phases II to III. Both the type of data, whether structured or unstructured, and cost emerged as key factors in the consideration of utilizing wearable in a clinical trials.<br>For pharma companies, wearables are improving internal processes through understanding patient biometrics and functionality from fitness tracking (accelerometry, step count, and calorie burn), heart rate, heart rate variability, and sleep, to more disease-specific biometrics including glucose monitoring, sweat analysis, electro-stimulation, UV tracking, and pressure sensors. To date, wearables are being used to support clinical trials across therapeutic areas from cardiovascular, neuroscience, respiratory, sleep, and stress to metabolic disorders, rheumatology, and pain. It is widely accepted that RPM in trials could save millions of dollars for pharmaceutical development, reducing the need for expensive tests being done in a clinic or hospital. Furthermore, clinical trial recruitment could become easier with the knowledge that patients no longer need to travel to the trial site, increasing the efficiency of trial recruitment and decreasing cost. Additionally, companies such as Litmus Health are creating data platforms to collect data from wearables and sensors, allowing sponsors to use the data to support clinical trials. Such platforms are essential for integrating real world data collected by wearables, while addressing issues with scalability and security. |
| Clinical Research | *"It has to have an API, so we have to be able to get data off the device. The more raw data we can get off, the better, so that will certainly increase our willingness to use data; if it's highly processed or if there's an opaque transformation process going on that makes us a little bit less excited. The price of the device is important, the ease of use, you know, how small it is, how it looks. I think those are all obvious things that are important."*<br>US Key Opinion Leader<br>*"My point of view has always been that we need to try to collect the best data in the best way possible in support of clinical trials because, when you don't do that, you put your clinical trial at risk, and then, you either collect data slowly or you collect data that is bad, or both, and then, you use those data to make decisions about a drug trials."*<br>US Key Opinion Leader<br>*"There's an enormous potential for wearables and sensors to help with patient-reported outcomes in other electronic clinical outcomes, assessment measures, and supportive trials. I think it's a huge area that's only going to grow."*<br>US Key Opinion Leader |
| Medication Adherence | Non-adherence to prescribed medication is one of the most challenging aspects of medicine. An amalgamation of sources, including a 2015 Survey by Omnicell estimates that 50-60% of patients forget to take their medication, with around 20% of patients incorrectly or inadequately taking their prescribed medications. Wearable technology has a great potential to serve as a reminder and track adherence in real-time. One example is MedTech's Leap Prescription Smartwatch monitors patient compliance by sending an alert when medication is taken incorrectly, with automatic notifications sent to the wearer's caregiver in the instance of noncompliance. Wastage of prescription medication has a negative outcome for patients, as well as economic impacts where in the UK, government figures estimate that unused prescription medicines cost the NHS £300M every year. There is currently a major gap in the market for wearable technologies that improve medication adherence, and while medication reminders are built in to many existing smartwatches and fitness trackers, the main users are younger populations. Other complaints of existing medication reminders are their bulky nature and requiring charging. There are unmet needs across all disease areas for more discreet devices, such as skin patches, with little to no battery requirements that can operate independently of smartphones.<br>*"Compliance is the most challenging aspect in my therapy area [obstetrics and gynecology]. Women tend to put up with their problems. Probably the most challenging thing is recognizing a problem and going to see someone in the first place."*<br>EU Key Opinion Leader |

Source: GlobalData

## 3.1 Technology Themes

The table below highlights the key technology themes impacting the global wearable tech in healthcare industry.

Table 2: Technology Themes

| Trend | What's happening? |
|---|---|
| Smartwatch Is King | Smartwatches in 2018 accounted for nearly 60% of the overall wearables market, according to GlobalData figures, mostly attributed to the remarkable performance of Apple Watches, Xiaomi-backed Huami's Amazfit, and Fitbit Versa. Samsung gained substantial traction in the market with its Galaxy Watch series, while Withings released its analog-style series of smartwatches. The growing inclination of consumers to access smartphone-like features from a watch remains the primary growth driver. Supplementing this factor, technological improvements such as seamless body integration, health and fitness information accessibility, and modular aesthetics are key growth stimulants for smartwatches' adoption. With improving adoption rate in the mature markets—GlobalData estimates over 10% of the adult population in the US will adopt smartwatches in 2019—competition in the segment is vastly increasing.<br>Traditional players Apple, FitBit, Garmin, and Polar all have products categorized as smartwatches; however, few have entered the health space, limited to Apple's Apple Watch. Moving away from purely fitness tracking, the segment is witnessing a significant surge in disease-specific functionality smartwatches, such as the medical-grade Embrace2 smartwatch by Empatica enabling continuous monitoring of sweat levels detecting the onset of epileptic seizures with an accuracy of 98%, according to its validation studies. Moving forward, GlobalData predicts that Smartwatches will be categorized based on functionality rather than the device type, with more wrist-worn devices in development that target specific diseases, their symptoms, and treatment compliance.<br>"*So all of the smartwatches, putting them under one category like 'smartwatch' is misleading because they have really distinctive roles when we look at them focusing in on their functions.*"<br>EU Key Opinion Leader |
| Custom Silicon Drives Smartwatches | While it is known that the smartphone component ecosystem played a critical role in getting the first wearables to market, the next wave of innovation is being driven by purpose-built silicon. Not only is Apple building unique processors and sensors into the Apple Watch, but the company is also using its own chips for implementation of Bluetooth in AirPod wireless headphones. Samsung is using its own Exnyos SoC for the Galaxy Watch, and Huawei has two custom chips in the Watch GT. Vendors that cannot compete with Apple directly for smartwatch processors are turning to Qualcomm. Unfortunately, Qualcomm's Snapdragon Wear 2100 is old and underpowered, and the 3100 is just catching up to the market. Qualcomm's Wear 2500 serves as a platform designed specifically for kids' watches. |
| Fitness Trackers Are Losing Out to Smartwatches | In Q4 2018, Fitbit derived 79% of its revenue from sales of smartwatches, while its fitness trackers segment contributed nominally. For the full year, 44% of Fitbit's revenue came from smartwatches—up from 8% in 2017, which clearly demonstrates the negative impact of Fitbit's legacy products and replacement of the same with low-margin smartwatches. Similarly, Garmin reported that the 25% growth in its outdoor segment during Q4 2018 was possible "with significant contributions from adventure watches." The shrinking popularity of fitness trackers in matured markets can be attributed to the rapid replication of their unique selling propositions (USPs) in smartwatches.<br>Overshadowing of fitness trackers' USPs such as step counts, calorie burns, sleeping pattern, distance walked/run etc., smartwatches now offer improved stats—for example ECG, non-invasive glucose monitoring, and fall detection—and social connectivity. These health-orientated applications allow more functionality specific to the consumer. |
| Smart Glasses Are Pacing Up Commercially | Eyewear is getting smarter, all thanks to augmented reality (AR) and virtual reality (VR). Despite the initial failure of Google Glass in commercial markets, it has maintained its position in healthcare and is a common feature in many teaching hospitals as a surgical training and assistance tool. Continuous investment from tech giants to develop and utilize AR and VR beyond the known areas of application, coupled with surging demand from enterprises, is propelling the growth of smart glasses. From first-person imaging to enhanced turn-wise directions, facial recognition, and health-sensing, AR is driving the penetration of smart glasses into multiple areas of the internet-connected society. Microsoft, Google, Lenovo, and Vuzix are leading in the AR smart glasses market, which is increasingly being challenged by new entrants such as Epson, Magic Leap, and Medical Realities. The recent entry of Facebook, Huawei, and Apple into the AR smart glasses arena serves as an additional boost to the emerging wearables segment. |
| Hearables Are Getting Smarter | Ear-worn devices are one of the first wearable technologies developed to enhance hearing. The dramatic surge in interest for combining hearing aids with entertainment attributes resulted in the inception of smart ear-wear, or "hearables," over the past three to four years. While the market remains in the early adoption phase, hearables offer infinite possibilities in the areas of healthcare and fitness. From heart rate measurements to sleep monitoring, steps and calories tracking, and brain waves analysis, hearables perform a variety of functions. The integration of Amazon's Alexa, Apple's Siri, Google Assistant, and IBM's Watson is making hearables smarter. Virtual assistants support the user as a "wise friend" by reading messages and weather updates, suggesting best sleep positions or cardio moves, translating a foreign language in real-time, and communicating with other smart devices, among others—all through voice control. Voice plays a crucial role in defining the relationship between the wearer and the device. Tech firms such as Apple, Google, and Samsung, among others, are harnessing the appeal and utility factors of these sensor-laden devices to the end consumers, with several |

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| | other firms already entering with biometric sensors such as Jabra, LifeBeam, and Vinci. |
| Smart Clothing to Gain Popularity | According to a survey by the World Economic Forum (WEF), 92.1% of corporate leaders believe that 10% of people will wear internet-connected garments by 2025. The market for smart clothing is in the initial experimental stages with few products, including NadiX yoga leggings, Sensoria socks, Ambiotex smart shirts, and Supa Bras, available commercially. The slow yet growing popularity of these products reflects a nascent demand for fitness-focused, sensor embedded, and internet-connected clothing from the mass market. In addition to sports and fitness, smart clothes are also being demanded in the healthcare and defense sectors, where continuous monitoring of body activities is of utmost importance. Start-ups are the key driving forces for the smart clothing segment, mostly attributed to their "Build-Your-Own-Device" approaches. Swayed by the response being generated by the start-up firms, tech leaders, especially Google and Samsung, are racing to establish their dominance of the emerging market. |
| Skin Patches | Traditional skin patches have been used for routine medical purposes including fixation of medical devices, simple drug release, and wound management. However, traditional medical patches are bulkier and wire-laden, requiring conductive gels, tapes and mechanical clamps which can hinder patient compliance, limiting their use over extended time periods. This is a space that has been calling out for innovation and has generated significant attention from investors and researchers over the past five years. As digital capabilities have improved, these formerly simple devices have evolved to facilitate more complex functions while being thin and flexible from being manufactured using nanomaterials, flexible electronic technologies, and sensors. Consequently, the definition of "skin adhesive patches" is broadening to include smart technologies allowing connectivity with IoT devices. GlobalData expects that miniaturization and lowered costs of development will create a surge for wearable sensors in healthcare, causing considerable market growth.<br>Currently, leaders in the space include small companies like iRhythm, based in San Francisco, which has launched its Zio single-use patch to monitor heart rhythms for up to 14 days remotely. |
| Disease Orientated Devices | Medical devices are one of the fastest growing areas within life sciences. When developing a wearable technology that targets specific health needs, understanding real-world patient needs is crucial. The industry is being driven to ensure greater inclusion of patients and consumers during the design and development processes. Without understanding real-world needs, consumers are unlikely to use the end product. Consequently, medical device companies are shifting their interest from device/consumable providers to disease/care management organizations. One example is the New York-based Peerbridge Health with its wireless device, the Peerbridge Cor System, offering portable ECG testing. With FDA 510(k) clearance, the wearable device is just one among a number of devices targeting AFib and other arrhythmias.<br>*"I'm trying to emphasize all the time that patient design should be at the core of any company working on wearables. Without the real-life clinical and medical life needs the patients to share with us, it's basically impossible to develop anything for them because they won't use it."*<br>EU Key Opinion Leader<br>*"They [companies] should focus on one thing, one real-world clinical need that they can address. Because some companies fall into the notion that they want to address five issues, from fitness to managing diabetes in one device. And that's physically impossible for now."*<br>EU Key Opinion Leader |
| AI and ML in Wearables | AI has been instrumental to the growth of wearables, mostly driven by the integration of virtual personal assistants such as Apple's Siri on its Watch and AirPod headphones, and Google's Assistant on Wear OS watches. While Amazon is not making wearables itself, Alexa is voraciously expanding across a wide range of wearable brands including Bose, Jabra, iHome, Linkplay, Sugr, and Bowers and Wilkins, among others. The only company with a strong AI assistant without a wearable in play is Microsoft; Cortana is only on PCs and connected speakers for now. However, more broadly speaking, AI is becoming a common feature across connected devices. In healthcare, it is enabling doctors to perform robotic surgery with precision, reducing the risk of post-surgery complications, and allowing surgeons to use AR and VR during surgical procedures and training exercises.<br>Start-ups lead in the space, equipping their wearables with AI-powered customized intelligent assistants that are mostly task-specific. Sensoria Fitness is one prominent example that provides consumers with Mara, an AI in-app coach to improve running routines using performance analytics. See our Thematic Report *AI in Healthcare* (GDHCTR006) and *Robotics in Healthcare* (GDHCTR007).<br>*"There's no way that we are going to be able to do healthcare the way we should without the help of AI and machine learning."*<br>US Key Opinion Leader<br>*"It's ubiquitous… I don't think wearables exist without machine learning. There is no success in the future of wearables without machine learning."*<br>EU Key Opinion Leader |
| Cloud Solutions and Wearables | The association of cloud solutions and wearables is being driven by a combination of the surging amount of wearables data, limited onboard storage, restricted processing capabilities and security concerns. Meanwhile, the evolution of wearables from consumer-focused devices into enterprise necessities is being driven by the need for real-time data access and computation— the competency of cloud technologies. In the long run, wearable-cloud setups will gain more prominence, especially in digital security, proximity marketing, and interaction with other IoT devices, while in the short term this association is only to benefit consumers and healthcare enterprises. In August 2018, Fitbit partnered with Google to use the latter's Cloud Healthcare API to connect user data with electronic medical records (EMRs). Combining |

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| | Fitbit data with EMRs will provide patients and clinicians with a more comprehensive view of the patient profile, driving more personalized care. |
| 5G – A Key Influence on Wearables | GlobalData sees 5G as a potential game-changer for wearables at both the development and adoption stages. The low latency and ultra-high reliability of 5G technologies are set to aid wearable designers in reducing the focus on storage capacity and processing power, both of which will be performed by the network itself. Similarly, at the adoption level, by leveraging its high bandwidth feature, 5G promises enhanced mobility, flexibility, and agility to consumers with self-contained wearables. While most wearables today are dependent on smartphones, tablets, and PCs, 5G will empower wearables with improved autonomous operability. Also, the development of 5G chipsets is set to drive further miniaturization of components and devices, thereby positioning wearables more integrally in enterprises—especially in healthcare. |
| 5G – A Key Influence on Wearables | The potential of 5G to support healthcare innovation services and IoT devices and to provide stable and quick enough connections to speed up the delivery of all internet-connected services, in turn, increases efficiency while driving down energy usage and cost. In clinical settings, faster connection speeds equate to better patient-doctor relationships through improved handling of patient data, refining all aspects of a patient's experience. All networks could be on one platform across medical devices and IoT and be capable of supporting more connections due to 5G's extensive broadcasting data. The connections will be more reliable, with the potential to transmit data across borders and between healthcare institutions around the world. Some drawbacks to 5G include investment in infrastructure, adoption of compatible devices, and questions to security around and inequity. GlobalData sees Huawei as better positioned to reap benefits of 5G in wearables, while American firms, especially Apple, will follow the Chinese giant.<br>*"I think that 5G is just really going to revolutionize the way we do everything… because 5G, with the speed of 5G, 100-plus faster with the bandwidth much broader, larger than what we have now, with the latency of now, which is imperceptible to the human senses, the 5G is really going to allow everything that we've been trying to do for the last 10–15 years is going to happen instantaneously. So from visuals to audio to data transmitting, to data analytics to activation of sensors or the activation of pumps, everything is going to be revolutionized… if it is as described, 5G is really going to speed up everything that has to do with digital, from remote surgery to remote advising to telehealth to the delivery of data, analysis of data, and responses."*<br>US key Opinion Leader |
| Moore's Law Applies to Wearables | As computing power and connectivity increase and the prices decline, designers can place sensors, processors, and displays in a more creative and valuable manner. The caveat is that this advanced cheap computing still requires electrical power, and battery technology is not advancing at the same pace. Due to variables of fashion and fatigue, wearables are even more limited by power consumption than devices that live in pockets or bags, which can be somewhat larger to accommodate bigger batteries. When applied to healthcare, this is especially pertinent, as to provide continuous monitoring of health parameters and biometrics, a device must be worn continuously — something currently unfeasible for the majority of devices. Although examples such as Matrix's PowerWatch 2— a fitness-focused smartwatch entirely powered by body heat and solar power—are emerging in the market, it is doubtful whether such technologies will improve self-containment of wearables in the coming years. |
| Sensors Hold Paramount Importance | Wearables are hotbeds for sensors: wearable devices being shipped today incorporate an average of 4.1 sensor elements compared to just 1.4 in 2013. Established sensors such as hearing aids, GPS, and thermometers are evolving, while newer wearables made with microelectronic mechanical sensors (MEMS) enable more advanced functionalities. Miniaturization and bundling strategies of multiple sensors are prime drivers for the development of more complex and capable devices in healthcare. Propelled by the surging demand for fitness, health monitoring, enhanced user interfaces, and haptic feedback support, wearable sensors are gaining importance. The main benefit of wearable health technologies is the ability to integrate multiple sensors, intelligent processing, and alerts, which support medical applications while interacting with health professionals. As sensors evolve, their long-term stability, resiliency, and biocompatibility will improve, as well as their size, functionality, and portability. GlobalData expects that these advancements in sensor technologies will allow wearable tech to further penetrate the consumer market with a high impact within the next 5–10 years.<br>*"I think it's going to take five years to work out some of the data standards and collection processes, and then, hopefully, over the next five years after that, it'll start to become completely pervasive so that, when people are going to the doctor, basically all their data are being collected in support of their care."*<br>US Key Opinion Leader |
| Smart Implants to Grow in Popularity | Smart implants are converting science fiction into reality by promising a wide range of benefits in remote monitoring, while fulfilling consumer-demanded characteristics of being low maintenance and seamless—complaints that have prevented greater uptake of wearable tech. Smart implants are being used in various parts of the body, with inserted chips measuring hormones and pH levels, blood glucose concentration, bacterial activities, electrical activities, and temperature, and even post-operative complications and rehabilitation, all the while gaining real-time biofeedback. Enterprises are more inclined to develop seamless interactive systems with the digital surroundings, thus ensuring the enhanced security of business assets and access control for employees. At present, without being "readily" removable, implantables sit outside of the wearable technology definition, despite many being minimally invasive and easily removable. GlobalData expects this area of digital health to grow as demand surges, but more slowly than wearables, given implants' regulatory and ethical implications.<br>Recent attention for the implantables segment has been heightened by Elon Musk's AI startup, Neuralink, announcing it aims to create a full brain-machine interface, with protocol versions in development. The interdisciplinary technology |

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| | demanded for this project includes robotics, software engineering, and neuroscience, with early designs featuring a micro-strip with hair-thin strands that can be implanted in the brain to treat brain injuries and diseases such as Alzheimer's.<br>*"Most patients stop using a device if they have to charge it every day, like in the case of the Apple Watch."*<br>EU Key Opinion Leader |
| Wearables and Bluetooth Low-Energy Controllers | Wearables are primarily communication devices and their need for an improved power supply is paramount. Owing to the limited hardware space, wearable OEMs are constantly on the lookout for miniaturized and powerful communication protocols that can operate on ultra-low power. The development of System-on-Chip (SoC)-based Bluetooth Low Energy (BLE) controllers is enabling OEMs to enhance power support to the devices, as well as to minimize device sizes and system cost. |

Source: GlobalData

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## 3.2 Macroeconomic Themes

The table below highlights the key macroeconomic themes impacting the wearable tech industry.

Table 3: Macroeconomic Themes

| Trend | What's happening? |
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| Demographics | The popularity of wearables with health applications is steadily on the rise in Western countries: ownership of wearables touched an average of 30% in the US, Spain, and Turkey in 2018. The Europe, the Middle East, Asia Pacific, and Latin America markets are dominated by male customers. In the US, the largest market for wearables, female adopters prefer productivity enhancement devices such as fitness trackers, whereas male adopters are more inclined to try smartwatches and smart glasses. In terms of age group, Millennials and Generation Z compose the key adopters for wearables, while Generation X and Baby Boomers are demonstrating growing interest. Wearable brands are carefully assessing the demographics in developing their products. While start-ups like Sensoria, Athos, and OMSignal among others are specializing in the niche products being demanded by Millennials and Generation X customers, established firms—Huawei, Samsung, Garmin, and Fitbit—are attempting to strengthen their positions in multiple growth areas covering all age groups.<br>*"Yet the majority of people with wearables are young people, so they don't tend to have these [chronic] diseases, but they are the future so their interest in their own health will be positive for their own future."*<br>EU Key Opinion Leader<br>*"I feel pretty optimistic for this area—it will just come as it will build from the young who are so used to technology."*<br>EU Key Opinion Leader |
| Wearables Benefit Enterprise | Wearable technology is helping to accelerate digital transformation for enterprise. Powered by a unique mix of robotics, alternative reality, IoT, sensors, and AI-supported virtual assistants, wearables offer enterprises significant solutions to process complex data sets in real time, thus driving augmented physical and perceptual capabilities of workers and enhanced safety measures. These devices primarily enable enterprises to streamline their processes, improve employee skills, reduce operation costs, and save substantial time—all of which directly support business growth. Wearables are expanding into a wide spectrum of enterprise applications propelling the inception of wearables-as-a-service (WaaS). As industrial and business use cases for internet-connected devices increases, companies have begun to implement wearables in the workplace. One such example is Dayton Regional Transit Authority's adoption of smartwatches to monitor employee health and provide the organization with powerful data points, as well as Aetna incentivizing the use of wearables with the promise of additional bonuses. Employee metrics being assessed include time spent sleeping to physical exercise, resulting in rewards for "favorable" behaviors. |
| Wearables and Customer Experience | Wearables hold substantial potential to transform contextual experiences into emotional, personalized experiences with great potential to keep patients and consumers engaged and invested in their personal health, mostly capitalizing on BLE usage and engagement. Driven by the association of wearables and BLE, consumers/ patients will benefit in the form of remote monitoring, decreased travel to appointments, more personalized experience, continuous monitors of more metrics, and ability of continuous monitoring by healthcare professionals. Wearables will eventually develop into mainstream instruments for all service-oriented industries such as banking, retail, entertainment, telecom, insurance, and healthcare.<br>*"I would like to see a greater emphasis put on engaging the consumers in their conversations... I think people will be more willing than people expect to participate if there's just a greater degree of transparency."*<br>US Key Opinion Leader |
| Wearables and Supply Chains | As patients increasingly use wearable technology and mobile apps in health monitoring and management, how healthcare services are administered is changing. For the supply chain directly, this will reduce pressure on doctors, medical professionals, hospitals, and pharmacies while allowing insurers to gain a more accurate picture of health information from the insured. The digitization of healthcare is already underway, with many patients and providers already utilized AI-powered healthcare services including home-based diagnostics, virtual health assistants (such as Babylon Health in the UK), as well as virtual nurse assistants. In the future, a doctor's role may evolve to providing more advanced care, where automated prescription services have the ability to modify prescriptions in real-time, accelerating the drug supply chain. Early adopters are set to position themselves better in the growing Industrial IoT ecosystem by leveraging wearable technologies. |
| US-China Trade War | The ongoing trade dispute between the US and China threatens to impact the wearables market negatively. The imposition of a 10% tariff on wearables categorized under "data transmission machines" is likely to push prices of these products higher in the commercial markets. While American firms such as Apple and Fitbit are concerned about the impact of the additional tariff, Chinese smartwatch maker Huami (exclusive tech provider for Xiaomi) is optimistic of growth. Huawei, the rapidly growing Chinese tech giant, is at the receiving end with no clear outlook of growth in the US market. Garmin's limited dependency on the Chinese market insulates it from encountering the sting of the tariff surge. |
| Equalizing Tech Maturity and Adoption | Technological developments and prospective applications of wearables are advancing faster than the anticipated commercial adoption rates. Despite rising awareness, the evolving states of wearable technologies coupled with privacy concerns are inhibiting swift growth of wearable devices in mass markets. Prospective customers of wearable technologies—except early adopters—are still unclear on what value these devices will add in their regular lives apart from fitness and socialization. Additionally, hospitals and healthcare providers are unable to fully realize the potential of devices in clinical practice due to lack of proper training on the devices and the integration of data into existing IT systems. The role of wearable OEMs is becoming |

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| | even more critical in ascertaining the value of wearable devices—beyond legacy tasks—to drive adoption. OEMs which hope to penetrate large, mainstream markets with smartwatches and glasses will have to create those markets. As technologies mature, enterprise applications increase and regulations pertaining to wearables get clear definitions, and adoption will increase. |
| Differentiation Is Necessary, Yet Invisible | With increasing competition, wearable OEMs are striving to differentiate their offerings from their peers. For companies entering the wearables market, differentiating their product from those already available is not only technologically difficult, but also expensive. While some early entrants excelled in differentiating their products in terms of aesthetics, followers are merely embracing the imitation model. For example, Apple Watch's rectangular and curve-edged look has become a standard design for several smartwatch OEMs. Apple's AirPods and Fitbit bands are also seeing imitation in the market, especially from smaller players. Smart glasses are the only segment maintaining some level of aesthetic differentiation, mostly because the technology is still in experimental stages. Meanwhile, price continues to differentiate, with wearable vendors setting prices of their products close to their competitors, leaving no space for new price slabs. While companies such as Xiaomi and Fitbit have attempted reducing prices to gain market share, Apple and Samsung have taken the premium pricing approach to position their products as luxury gadgets. |
| Wearables and Customer Loyalty | "Customer Loyalty" lies at the heart of the success of wearables. As the wearables market continues to gain momentum, retention of customers and development of a sustainable growth model are key parameters for wearables brands. Customer loyalty programs pivot around offering incentives to customers, which enhances the product appeal and entices repeat purchase. The Fitbit Reward Program, launched in March 2019, incentivizes customers with points to avail discounts at its partner brands, namely Adidas, Blue Apron, and Deezer. Apple, on the other hand, offers discounts for exchange purchases of Apple products. This trend is set to grow as competition increases and adoption improves. Incentives to understand health for consumers and patients remain under-developed and limited to insurance policies, corporate schemes, and distinct geographies such as Scandinavia where incentive structures for physicians to use digital health technologies and learn about them are in place. This, in turn, encourages patients to use them, as they are seen as "partners," where questions around the technology flow bilaterally, growing the customer base in health from multiple areas. |
| Child Care – a Key Driver for Smartwatches | Smartwatches not only promise benefits to healthcare, but also child care. The parental outlook of introducing children to technology by body-worn gadgets is fueling growth in the wearables market. Bundled with entertainment, learning development exercises, and location tracking solutions, among others, smart wearables are progressively gaining traction worldwide. Features such as 4G and upcoming 5G connectivity, Wi-Fi, GPS, Bluetooth 4.0, voice call, step counting, parent-child navigation, SOS button, home and power button, voice assistant, shake & add friends, and rejecting unknown numbers, among others are becoming common features in kids' smartwatches. Fitbit, Xiaomi, Huawei, Garmin, Tencent, and LG, among others, are banking on this population to gain early penetration advantages in the market. The Chinese wearables market is primarily capitalizing on the child population. In Q4 2018, of all wearable devices sold in China, approximately 30% were targeted at children, of which around 40% were noted to be 4G enabled. |

Source: GlobalData

## 3.3 Regulatory Themes

Regulations surrounding wearables are in flux. While some regulatory agencies view wearables as low-risk devices and avoid regulatory tagging, some are clearly ignorant of the potential security issues associated with wearable devices. Thus, wearable OEMs are increasingly becoming liable for the protection of public data.

Table 4: Regulatory Themes

| Trend | What's happening? |
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| European Union | All around the EU, concerns of protecting mHealth data—generated through body-worn fitness gadgets—are increasingly becoming vital. To avoid the risk of data manipulation and misuse, the General Data Protection Regulation (GDPR) framework makes it mandatory for wearable users to be aware of what data is being accessed by which app. Meanwhile, the supply chain stakeholders—including OEMs—are being compelled to stringently follow the rigorous concept of "data protection by design and default." Owing to the unavailability of 100% secure systems to protect data, the "data protection by design and default" approach intends to reduce the proportion of data loss in events of breach or malfunction. Under the approach, GDPR overtly necessitates that the only personal data processed are those necessary for each specific purpose of the processing. This requirement includes the amount of data collected, the storage time, the level of processing, and the accessibility of the data. Facing previous challenges in preventing personal data, companies such as Fitbit and Google have swiftly redesigned their privacy policies. Apple, Samsung, and other wearable OEMs are also adopting newer dynamic policies. For enterprise adoption, GDPR mandates employers to perform a Data Privacy Impact Assessment (DPIA) to assess the necessity and proportionality of their technology plans. DPIA demonstrates the employer's risk assessment pertaining to the use of wearables and supervises the balance between employee privacy and the protection of business interests. As the European wearables market is still in the early stages, these regulations are certain to undergo amendments as adoption paces up in the coming years. |
| US | Low-risk general wellness wearable technology including fitness and smartwatches is normally not subject to regulation by the FDA; however, recent releases like QardioCore and AliveCor's Kardia products have been granted clearance by the FDA as mobile ECG sensors to detect heart disease, anxiety, and more. This represents a move forward by the FDA where it is stepping up its regulatory oversight to provide guidance. The FDA views wearable devices as "general wellness" products that promote wellness and present very low risk to the user's safety, thus they refrain from regulating wearable devices. Taking security and privacy concerns into account, wearable OEMs are either self-regulating their offerings or fitting into medical device compliance guidelines. Although wearables are not defined under any US Federal law, Protected Health Information (PHI) is subject to regulation by the Office for Civil Rights (OCR). Any wearable OEM found sharing PHI with Covered Entities such as health plans, health care clearinghouses, and healthcare providers is punishable by the OCR. This also applies to third-party partners of both wearable OEMs and Covered Entities. Thus, cloud service providers partnering with wearable business associates are directed to provide Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance as an add-on feature, as well as to sign Business Associate (BA) contracts as part of the deals. US wearable OEMs are thus enjoying more relaxed operational conditions in their domestic markets compared to in the EU. Any data collected using the wearable device is protected by HIPAA only when shared with medical establishments.<br>*"Everybody, of course, needs to conform to standards of HIPAA and being able to make sure that all data are collected either in a completely de-identified way or according to rigid HIPAA guidelines. But beyond the standard requirements for collecting data, there have not been a lot of data-standardization push for wearables."*<br>US Key Opinion Leader |
| Digital vs. Traditional Healthcare | Traditional regulation of medical devices relies on devices meeting conformity standards and manufacturers supplying the safety and efficacy data from extensive clinical trials to regulators. However, these traditional means of assessing safety and efficacy are being overtaken by the pace of technology development. Regulators have accepted that traditional healthcare with its existing regulatory process does not fully support digital change, where there is currently little harmonization or convergence of medical device guidance or regulations. This fragmentation is challenging for companies in the space, which are either designing devices to avoid the complex regulatory process or taking advantage of ongoing developments and designing devices to fit in existing regulatory guidelines. As wearable technology matures, there is an opportunity for tech companies, developers, and healthcare bodies to be more involved in the design of future regulatory frameworks, where companies will have more of an influence on the regulatory outcome.<br>*"What I don't think we should expect though is that people validate these devices against all of the traditional metrics."*<br>US Key Opinion Leader |
| Data Security as a Critical Issue | Data security trends include the changing nature of cyber threats, the evolution of key cybersecurity technologies, industry growth drivers, healthcare governance trends, and cybersecurity trends in healthcare. Ransomware, insider and privilege misuse, denial of service attacks, "hacktivist" groups, and online fraud have all significantly increased in the past five years. During one recent healthcare breach, as many as 79 million patient medical records were affected. Breached patient records tripled in 2018 compared to 2017, with 51% of violations a repeat offence, continuing the trend of at least one health data breach per day (JAMA, 2018). |

Consequently, threats to patient information undermine public trust. While more recent regulations have responded with the introduction in the EU of the Directive on Security of Network and Information Systems (NIS), adopted by the European Parliament in July 2016 and aiming to harmonize EU cybersecurity regulations. The General Data Protection Regulation (GDPR), which came into effect in May 2018, acts to protect and empower EU citizen data privacy and enforce structural changes in the way that organizations approach customer data privacy and protection. Under GDPR, non-compliant organizations could suffer fines of 4% of their annual turnover or €20M ($22.3M), whichever is highest. In the US, cybersecurity regulations are less strict at the federal level compared to Europe. The National Institute of Standards and Technology (NIST), a unit of the US Department of Commerce, has a code of best practices called the NIST Cybersecurity Framework; however, this is not mandatory. Currently, 42 out of 50 states have introduced more than 240 bills related to cybersecurity, so adhering to standards is improving and changing. Tech vendors are being compelled to adopt “privacy by design” techniques during product development and “Privacy-as-a-Service” over the product life cycle. Users are advised to update their devices with the most recent firmware and to avoid accessing malicious versions of legitimate applications. For medical devices, there is no specific regulation in place, just guidance over assets, threats, and vulnerabilities. See our Thematic Report *Cybersecurity* (GDTMT-TR-S175) for more on this theme.

*“Technology can achieve more in terms of data security, ensuring data security than any manual process that we have implemented in the past. I think, actually, technology will make sure that we have objective guarantees of data privacy, rather than being a risk.”*

EU Key Opinion leader

Source: GlobalData

# 4 Value chain

Building wearable technology in healthcare varies in terms of complexity. The more simplistic technologies such as smartwatches tracking heart rhythm have been on the market for years, whereas newer, more sophisticated wearable technologies such as complex sensors and skin patches require an extensive new supply chain. Depending on the application, level of sophistication, and reliability requirements, wearables generally involve levels of regulatory oversight, control, and processing, with in-built hardware and software, and increasingly requiring reliable connectivity moving further toward cloud processing.

Wearables need to be able to sense minute changes in the user's body and its surroundings. Depending on the applications, they need sensors that are sensitive to touch, heat, light, vibration and sounds, or even certain chemicals. Each of these sensors is made by specialist manufacturers that have their own R&D priorities and evolution.

Mechanical components are another important element of a wearable item. These need to be precise, reliable, and strong, while consuming minimal power to avoid frequently re-charging batteries, which has emerged as a common obstacle to adoption. In many cases, devices need to be continuous in order to monitor health status at an activity/fitness level and increasingly at a medical level to provide accurate data to clinicians with the potential for earlier diagnostic capability and guidance of treatment. Above all else, they need to be simple to use, with effortless integration that fits seamlessly into users' everyday lives.

*"In my experience, those [existing] devices still tend to be a bit clunky and a bit difficult to use, they don't have great battery life, they're a bit unwieldy, patients don't necessarily like to be seen wearing them."*

US Key Opinion Leader

*"It has to be seamless. It has to be invisible. I don't want any patient to think that they should be actively using these technologies."*

EU Key Opinion Leader

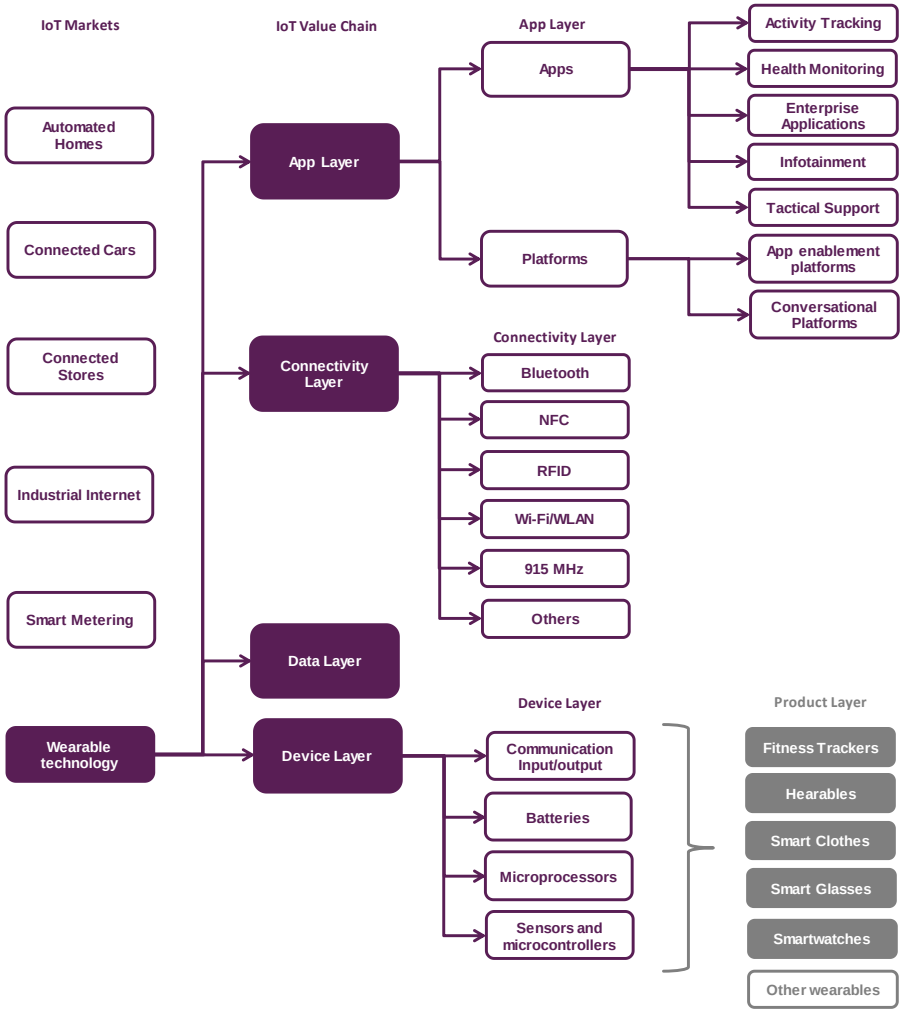
*"Technology needs to be simple for compliance, really simple. It's simply no good having something where the battery is short. It has to be incredibly simple, shockingly simple really."*

EU Key Opinion Leader

The schematic below highlights how wearable technologies fit into the IoT value chain. As described in the recent GlobalData Thematic Report, *Internet of Things* (GDTMT-TR-S176), we classify the IoT into six distinct markets: automated home, connected car, connected store, industrial internet, smart metering, and wearable technology. For the purposes of this report, we exclusively focus on the wearable technology market. However, it is important to note that each of the six IoT markets has a common value chain that can, in turn, be split into four layers: the app layer, the connectivity layer, the data layer, and the device layer. These layers are logically discrete, although large-scale IoT use cases will likely result in these

logical boundaries becoming blurred. For example, while there is a continuous investment to identify the data layer towards the top of the stack, a growing proportion of the data processing is taking place within, and at the edge of, the network

Figure 2: Wearable Technology Within the IoT Value Chain




Source: GlobalData

## 4.1 IoT Value Chain

### 4.1.1 App Layer, Apps, and Conversational Platforms

The application layer is the seventh layer of the Open Systems Interconnection (OSI) and is responsible for direct interaction with end-users. The layer focuses on process-to-process communication across an Internet Protocol (IP) network and to develop end-user services. This layer is increasingly attractive to service-focused companies and is gradually shaping up into the most profitable segment in wearable devices. The app layer can be split into two segments: the apps themselves, which are software products designed for a single purpose; and platforms, which serve as ready-made enabling environments within which apps can run.

Apps as a whole are the engagement accelerators on wearable devices that users communicate with. Commonly, apps in contemporary wearable devices within healthcare cater to activity tracking, health monitoring, disease awareness, support for treatment, and support for caregivers and clinical personnel. The number of digital health applications available in the market has increased significantly over the past three years. For example, in the UK, the National Health Service (NHS) currently hosts a Beta site Digital Apps Library, where it lists its 70+ "NHS approved" medical apps across therapeutic areas from COPD to dementia (NHS, 2018). As more apps are developed, in turn, wearables can perform more functions, driving increased demand.

The most popular applications fall into the following categories:

- Activity Tracking – Monitors functions such as steps, sleep pattern, heart-rate and calorie intake. These apps intend to provide users with instant feedback to modify their physical behavior for healthy living.
- Health Monitoring – Supports medical diagnosis of user's health conditions. Recently introduced ECG and glucose monitoring features on wrist-worn wearables fall under this category. Additional features of such devices include providing users with disease updates, news, informative articles, treatment plans, drug information and advice.
- Therapeutic Wearable Medical Devices – Provide real-time monitoring of patient metrics relating to disease therapy. Such wearables are often used in conjunction with internal or implantable biosensors such as digital therapeutics (more information in GlobalData's Thematic Report *Digital Therapeutics (DTx)* [GDHCHT025]). These apps create seamless connectivity between individual patients, real-time monitoring of medication adherence, and remote monitoring. These have most widely been used within clinical trials or for patient populations and therapeutic areas with a high risk of non-compliance such as the psychiatric patients, elderly, young, and other vulnerable populations.

At the platform level, app enablement platforms are software products that lay the foundation capabilities for developers to create task-specific, consumable apps. Traditional leaders (Apple's watchOS, Google's Wear OS, Fitbit OS, and Samsung's Tizen) continue to dominate the market, especially within the smartwatches segment. Another category of platform is the newer conversational platforms driven by AI and ML technologies. These include voice recognition, natural language processing (NLP), and contextual awareness. Amazon's Alexa is at the forefront within conversational platforms, have

numerous collaborations with health and pharma offering the 'Alexa Healthcare skills' from automated home prescription delivery to rehabilitation services. While Google Assistant is making a substantial push to gain traction, it remains far behind Amazon Alexa at present.

### 4.1.2 Connectivity Layer

Utilizing advances in sensor technologies and communication systems, wearables are accelerating deeper connectivity of humans with their digital surroundings. While most wearables are dependent on smartphones for real-time communication, advances in connectivity mean that body-worn devices can become completely autonomous.

The highest growth within the microelectronic mechanical systems (MEMS) market is being driven by consumer electronics, attributed to the advancements in wireless communications technology. The end user benefits from ongoing improvements to Bluetooth, Bluetooth Low Energy (BLE), Radio-Frequency Identification (RFID), Near Field Communication (NFC), Wireless Fidelity/Wireless Local Area Network (WiFi/WLAN), and 915 MHz (ISM Band), which connect with smartphones. USB and Ethernet are also used to establish connectivity between wearable devices and smartphones, mostly for devices that do not require real-time communication. BLE is the most common technology used in contemporary wearables due to its low power consumption. As traditional Bluetooth consumes more power, wearables designers see BLE as the most suitable alternative for constant connectivity with cloud solutions. NFC also finds substantial applications in modern wearables, mostly in transaction-related applications such as contactless payments.

In addition to the lower power consumption, advancements are improvement performance within MEMS sensors. More efficient antenna frequencies operate with moderate loss in comparison to older models, changing antenna frequencies that mean devices operate more efficiently. The improvements in power usage and performance provide excellent linearity between multiple connected devices, opening the market to numerous types of devices to operate either autonomously or collectively. In healthcare settings, improving connectivity is a key driver amongst developers given the complex nature of health monitoring and disease management care.

*"Synchronization issues with Bluetooth and the lack of gamification that I've seen these companies that can make these patients keep using the device for more than three or six months."*

EU Key Opinion Leader

*"There is a huge amount of work on connectivity across different aspects of social care a hospital services, and that's really important but nothing very technological or innovative about that. That should have happened years ago."*

EU Key Opinion Leader

### 4.1.3 Data Layer

The wearable data layer serves as the storage and computation location. Data generated by embedded sensors are automatically stored in encrypted databases and processed through apps, with the resulting data transmitted to a remote server. Computation tools and machine learning software analyze the data, which is further transmitted back to the user/s, either through an official web account or on the device itself via the same channel of apps. Competition in this area is on a steady rise, as tech giants continue to expand their cloud infrastructure worldwide and simultaneously invest in the development of AI tools for data analysis. Amazon, Microsoft, Google, and IBM are well-positioned players in this area and are already providing support to numerous wearable vendors and service firms. Chinese cloud providers are also racing to grab the opportunity; however, they are restricted by US and European regulatory authorities on national security grounds.

Recent moves to better protect patients' health data have been developed, with cloud providers required to comply with HIPAA and FDA Code of Federal Regulations Title 21 Section 11. Healthcare-specific, cloud-based services now include infrastructure as a service within hospital settings, and software as a service (SaaS) for EHRs, increasing functionality while adding value to health IT departments, which are notoriously slow to adopt new processes and a major barrier facing emerging technologies.

## 4.2 Device Layer

As exhibited in the diagram above, the device layer can be subdivided into four categories:

- Communication input/output hardware – short-range radio or other wireless protocols, as well as wired connectivity through a USB port, are the electronic systems that enable communication to and from wearables.
- Batteries – rechargeable power sources that enable operation of the device.
- Microprocessors – integrated circuits (chips) that can be programmed to run the software.
- Sensors and microcontrollers – sensors such as gyroscopes, accelerometers, electrodes, recording data including temperature, proximity, humidity, pressure, and altitude, detect and respond to input from the physical environment while microcontrollers are used to direct the features and actions of a device.

Features from device layers are seen across device types, which we categorize wearable technologies into the product layer where we look into the end products: hearables, smartwatches, AR smart glasses, VR smart glasses, fitness trackers, smart wear/smart clothing, implantable devices, and skin patches. These devices can also be either categorized as diagnostic and monitoring wearable devices, like the FitBit, Omron, Nemaura, and MC10, or as therapeutic wearable medical devices, such as the Medtronic MiniMed insulin pump. To date, marketed end products have mostly been diagnostic and monitoring devices, which are further segmented into vital signs monitoring devices, glucose monitoring devices, sleep monitoring devices, fetal monitoring and obstetric devices, and neuromonitoring devices. While limited at time of writing, therapeutic devices can be categorized into pain management devices, rehabilitation devices, insulin pumps, and respiratory therapy devices, which provide RPM and medication delivery.

### 4.2.1 Hearables

Hearable technology has gathered significant attention since the success of Apple's AirPod wireless earbuds, predicted to be the next big thing in wearable technologies. In the consumer electronics market, several other firms—Samsung, Google, Sony, Jabra (GN Group), and Nuheara—are progressively investing in the in-ear computing devices. Steady efforts amongst developers aim to drive hearables beyond their legacy utilities of music amplification and phone calling capabilities into more convenient application areas such as hands-free directions, biometric measurements, guided fitness and wellness coaching, and online purchasing, among others. Although hearables with health purposes are in the early stages of development and their future efficacies are largely unknown, the devices hold potential to significantly impact the markets for smartwatches and fitness trackers on maturity. While competition in this segment will certainly grow in tandem with technological maturity, we foresee the tech predators—Apple, Google, and Amazon—to undertake aggressive consolidation initiatives to absorb promising start-ups and strengthen their market positions. Traditional audio companies such as Bose, Sennheiser, and others are set to gain newer spirits of integrating sensor driven capabilities in their already renowned tech competencies.

Within health, traditional hearing aid brands hold FDA approval for hearables and naturally occupy a significant share of the hearables market (Resound, Oticon, Phonak, Signia, Starkey, and Widex). While these devices have the ability to connect with smartphones for improved control, they are not geared towards the wider consumer. Electronic manufacturers have entered the market with hearables measuring biometrics from vital signs (heart rate, body temperature, blood pressure, pulse oximetry, ECG, and electroencephalogram signals) to activity tracking, biometric personal identification (NEC), discreet wear, augmented hearing (such as Doppler Labs), and even translation.

Apple maintains a leading position in the market, with their patent for a "Sports Monitoring System for Headphones" and AirPods, along with Samsung and Google, while Huawei, Sony, and Bose utilize their tech legacy to develop wearable tech products. Below are some of the challengers in the market.

Table 5: Top Hearables

| Company | Function | Features | Regulatory Clearance |
|---|---|---|---|
| Bose SoundSport Pulse | In-ear Activity Tracker | Heart rate monitoring | N/A |
| Cosinuss One | In-ear Activity Tracker | Body temperature and heart rate monitoring | N/A |
| Halo Sport | Neuropriming Headphones | Neuropriming for athletes using electric currents to control movement | N/A |
| iRiver On | Heart Rate Monitoring Earbuds | Monitors heart rate, tracks distance traveled, and other biometrics | N/A |
| Jabra (GN Group) | Fitness Tracking | Waterproof, personalized audio coaching, race pace calculator and recovery advice | N/A |
| Kuaiwear Kuai | Multisport Biometric Headphones | Monitors heart rate, VO2 max, speed, distance, cadence, calories burned | N/A |
| LifeBeam | AI-powered fitness tracking | Heart rate sensor, connected Vi Trainer for immersive training experiences | N/A |
| Mymanu | Voice Translation Earbuds | Translates voice in real-time with advanced audio quality | N/A |
| Nuheara | Amplification Earbuds | Analyzes hearing to ID unique hearing profile, amplifies sound for optimum sound delivery | N/A |
| Vinci | Artificial Intelligence Headphones | Heart rate monitoring, 32 GB storage, noise-canceling | N/A |

Source: GlobalData



### 4.2.2 Smartwatches

Consumer-grade smartwatches have accelerated in popularity and functionality since 2014. The underlying technical function has improved, along with acceptability and effectiveness in tracking everyday fitness and activity, enabling consumers to become more self-aware and promoting the culture of the “worried well.” Big tech players like Apple, Samsung, FitBit, and Garmin have dominated the market with their predominantly fitness-tracking smartwatches. In 2010, players entered the market with additional features such as heart rate monitoring, location tracking, and accelerometry to become more holistic health trackers and even medical devices.

Smartwatches with disease-specific functions are on the rise, with more individualized health monitoring. Data collected by the smartwatches is synched with apps which either analyze or send metrics to a platform for analysis by an HCP or caregiver. The biggest progress for smartwatches in the health arena is cardiovascular indications. Omron’s HeartGuide smartwatch launched with its clinically accurate blood pressure monitor and ECG, providing complete oscillometric blood pressure monitoring to provide clinically accurate heart data, blood pressure readings, fitness and activity tracking, and enabling connectivity with a mobile app and Amazon Alexa Skill. A cuff in the watch band inflates to capture systolic and diastolic pressure, taking oscillometric measurements using the same method used in medical-grade blood pressure monitors. Supporting research includes peer-reviewed clinical validation studies with each model tested according to the protocols of the Association for the Advancement of Medical Instruments (AAMI), the European Society of Hypertension (ESH), and the British Hypertension Society (BHS), with the FDA providing the device with 510(k) clearance in 2019. Other

players in the space provided with 510(k) clearance include the KardiaBand from AliveCor with its technology for taking ECG readings, and its accompanying KardiaMobile that monitors users at risk for heart disease or stroke by detecting arrhythmias.

Chronic conditions are primed for disruption including diabetes, a market where continuous blood glucose monitoring is essential, along with obesity tracking and nutrition advice. The sugarBEAT watch by Nemaura enables continuous blood glucose monitoring (GCM) in diabetic patients. Its wireless, non-invasive GCM incorporates BEAT Technology, a reusable electronic sensor with a daily disposable adhesive skin patch that draws a small amount of glucose into the patch from the interstitial fluid of the user, measuring the amount of glucose in five-minute intervals. This eliminates the need for routine daily finger prick calibration, an aspect of current GCM that causes discomfort to patients and, for some, physical resources by caregiver or HCPs. The device has been given a CE Mark in the EU for its novel and non-invasive CGM functions.

Smartwatches are entering the market with application across disease areas such speech therapy, seizure detection in epileptics, posture aid, and respiratory tracking. One leading device in the epilepsy field is Empatica's Embrace watch, which monitors physiological stress, arousal, sleep, and physical activity, sending an alert to patients and caregivers when unusual activity is detected, such as a convulsive seizure. The user's electrodermal response sensor is set to a pre-set level customized to the patient history and health profile, allowing for personalized usage. Both the FDA and EU permitted 510(k) and CE marking clearance in 2019 owing to its clinical testing in an epilepsy monitoring (EM) unit among epilepsy patients, whereby Embrace detected generalized tonic-clonic seizures with an accuracy rate of 98%.

As smartwatch adoption continues to increase, while lower-priced competitors and reduced manufacturing and component costs will disrupt the market with lower prices; meanwhile, functionality will increase, creating a more fragmented market.

Table 6: Top Smartwatches

| Company Product | Function | Feature | Regulatory Clearance |
|---|---|---|---|
| AliveCor KardiaBand/Watch | ECG-monitoring equipment watch | KardiaBand with six-lead ECG to detect abnormal heart rhythm and AFib consistent with existing KardiaMobile products and wearable device | 2019 US FDA 510(k); EU CE Marking |
| AppleWatch | Fitness and activity-tracking watch with ECG monitoring | Electrical heart sensor detects abnormal heart rhythm and AFib, along with fitness tracking, fall detection, and SOS | 2018 US FDA 510(k); de novo (DEN180044) |
| Empatica Embrace 2 | Wireless wrist watch for epilepsy management | Monitors physiological stress, arousal, sleep and activity; electrodermal response reaches a pre-set level (abnormal) alerts user/caregiver | 2018 US FDA 510(k) (K172935); 2017 EU CE Marking |
| Garmin | Fitness and activity-tracking watch | Tracks and shares distance, pace, heart rate, and calories data | No |
| KinesiaU | Diagnosis of Parkinson's disease, tremor detection | Sensor measurement of tremor, slowness, and dyskinesia for movement disorders; tracks symptoms in real-time, in response to therapy and activities | 2019 US FDA 510(k) |
| My SugarBEAT Watch by Nemaura | Continuous blood glucose monitor watch – diabetes | Sensor with daily disposable adhesive patch draws in glucose from the interstitial fluid and measures it at five-minute intervals; sends data to an application for analysis for diabetics, athletes, and intensive care | 2016 EU CE Marking |
| Omron Heartguide | Clinically accurate blood pressure monitor and ECG – intended to prevent stroke and heart attack | Oscillometric blood pressure monitor provides clinically accurate heart data with a mobile app and Amazon Alexa Skill; blood monitors blood pressure, fitness and activity, and sleep patterns | 2019 US FDA 510(k) |
| OnePulse Smartwatch | Health Monitor Watch | Monitors heart rate, activity, sleep patterns, and location with real-time alerts, medication reminders, and auto prescription refills; connects with EHR platforms | US FDA 510(k) |
| PKvitality | CGM Watch for Diabetes | Micro-points and biosensors detect glucose levels, track steps taken, distance, and calories | EU ETA 2022 |
| Samsung | CardioBand ECG | Displays ECG rhythms and detects arrhythmias. Used for cardiac rhythm discrimination between normal/AFib/abnormal | 2018 US FDA 510(k) |
| SmartMonitor | Watch Detects Repetitive Shaking Motion for Seizures | Monitors the wearer and detects repetitive shaking motions similar to those caused by seizures, alerting user and caregiver when necessary; detects heart rate, location, and activity | No |
| Study Watch by Verily Life Sciences | Wireless Monitor for Pulse, Heart Rate, Electrocardiogram (ECG) and Skin Temperature | Monitors pulse, heart rate, ECG, and skin temperature; tracks external changes the patient's body such as noise levels and light exposure, and provides a real-time data about a patient's activity and vital signs. | 2019 US FDA 510(k) (K182456) |
| Viatom Checkme O2 | Wireless Wrist Pulse Oximeter | Tracks and monitors heart rate, QRS duration, ST segment, and rhythm analysis; ECG SpO2, pulse oximeter, activity tracker, thermometer, and a sleep monitoring device | No |
| Withings | Fitness and Activity Tracking Watch with ECG Sensor | Heart rate and activity tracking with sensor measuring ECG for AFib | No |
| Xiaomi | Huami Amazfit Health Band with Heart Rate Monitor | Provides movement tracking and fitness analysis; screens heart rhythm and sends an alert if an arrhythmia including AFib is detected | US FDA ETA 2019 |

Source: GlobalData

### 4.2.3 VR & AR Smart Glasses

Advancements in VR and AR are realizing value in healthcare. VR describes devices that enable the user to view and interact with immersive computer-generated environments, whereas AR allows users to see their real-life environment with simulated elements added by the computer and viewed through a mobile phone, tablet, or AR glasses..

VR technology is used in medical practice to aid surgical procedures and training, removing the necessity to work with real-life tissues, thus reducing error. VR enables surgeons and medical educators to build virtual organs and tissues, benefiting the clinicians and medical students directly, enabling better communication with other HCPs and patients through low-cost, non-invasive means. Its applications stretch across healthcare from medical rehabilitation, consultations, and diagnosis to wider education and training. Applications in healthcare practices include the Limbix company using VR exposure therapy to treat anxiety disorders such as acrophobia. In medical education, many companies, such as the Surgical Theater company, are applying VR technology for anatomy and surgery simulation.

AR expands or enhances reality by combines VR technology with real-world, real-time experiences in 3D space. AR is divided into 3 categories: marker-based, markerless, and location-based services (geolocation or mobile location). Applications in healthcare practices include using AR for phantom limb pain treatment and autism treatment. Within medical education, applications of the technology include AR anatomy teaching, allowing for a greater impact and understanding. According to the company Medical Realities, students surveyed on the use of AR/VR for teaching anatomy and surgery procedures reported a significant increase in the content they were able to remember, in most cases above 50% more than traditional teaching methods.

Additionally, new trends that combine VR and AR, termed “mixed reality” or MR, have surfaced. This provides a more realistic and highly interactive experience for users, with traditional tech companies such as Microsoft, Acer, and other manufacturers beginning to release MR technologies.

Table 7: Top AR/VR Smart Glasses

| Type | Company Product | Function | Feature | Regulatory Guidance |
|---|---|---|---|---|
| AR | Brain Power | Brain Power Digital Coach-Autism | Teaching social-emotional skills for autism or ADHD | No |
| AR | Epson | Medical Imaging Data | Enables clinicians to visualize and accesses medical imaging data and support management, visualization, augmentation ,and navigation of diagnostic imaging data for a broad range of clinical procedures | CE Mark ETA 2023 |
| AR | eSight Glasses | Vision Restoration Glasses | Improves vision in people with low vision capabilities and aids in restoring vision | 2017 CE Mark |
| AR/ VR | Immersive Touch | Medical Imaging Information and Surgical Assistance | Helps surgeons to visualize patient anatomy, provides patient-specific 3D/haptic models directly from CT/MRI data; allows pre-visualizing planned surgical intervention and explores the patient specific anatomy | 2015 FDA 510(k) |
| AR | Magic Leap | Medical Imaging Information and Surgical Assistance | Enables clinicians to visualize and accesses medical imaging data and support management, visualization, augmentation, and navigation of diagnostic imaging data for a broad range of clinical procedures | CE Mark ETA 2023 |
| VR | Medical Realities | Medical Imaging Information and Surgical Assistance | VR for surgical training augments reality for education and training | No |
| VR | Osso VR | Medical Imaging Information and Surgical Assistance | Virtual operating room with controllers that track 1:1 with real-life hand movements and respond with feedback mimicking the procedure | No |
| VR | VirtaMed | Medical Training | Surgical simulators for medical training | No |
| VR | VirZOOM | Fitness | Games made for active motion control where pedaling and leaning propel the users | No |
| AR | Vuzix Blade | Telemedicine Glasses | Provides telemedicine for the transmission of digital imaging, video consultations, and remote medical diagnosis through smart glasses | FDA ETA 2019 |

Source: GlobalData



*"I think that the smart glasses are really the natural evolution of the computing device… In healthcare, Google Glass, for example, has been very active with virtual scribes, improving the patient-doctor relationship and the communication during an interview with a patient and physical exam and populating the electronic medical records and preventing errors and decreasing costs and improving the quality of time that the patient or the provider shares. And like Google Glass, there are others. There is a Vuzix Blade device and there's an Epson device… That device [head mounted wearable] is going to be a wearable device and a portable computer/smartphone where most of the need for digital interaction that we will do is going to be through a device like this. In many, many instances of the healthcare ecosystem, from the clinics, to the floors, rounding, to the operating room, to the recovery room, even the home care, I think there's really no limit to what we can do with this device."*

US Key Opinion Leader

### 4.2.4 Fitness Trackers

Consumer-grade fitness trackers are targeted at customers comprising athletes, sportspeople, and outdoor adventure lovers, among other health-conscious segments. Developed to provide accurate fitness-related metrics and encourage healthy lifestyle, fitness trackers are marketed as digital connectivity devices and position themselves as alternatives to wristwatches. Evolving from pedometers, the present-day fitness trackers incorporate a myriad of sensors to calculate mileage, record calorie expense, and also to monitor heart rate and sleep quality. Aspiring to aid healthcare, modern fitness trackers are increasingly being packed with biochemical sensors that are capable of alerting to a medical problem by reading core body vitals. Fitness trackers are expanding into more user-friendly devices—primarily demanded by Generation Z consumers—by means of combining the concepts of fitness with infotainment and social media. All devices are powered by rechargeable lithium ion batteries and operate in sync with smartphones via Bluetooth to deliver comprehensive reports of the user's workout performance.

Fitbit, Garmin, Samsung, and Xiaomi are the most well positioned players in the fitness trackers domain, with several others—Strava, Misfit, GOQii, and Huawei—swiftly gaining traction. While the leading players are diversifying into the smartwatches segment, their fitness trackers are continuously gaining technological prowess, thus enabling segmental growth. While their health-related value hasn’t yet been fully realized, it is expected that these devices will have a role to play in preventive health services—for example monitoring cardiac and metabolic disease markers, with step counts assessing relationships between physical activity and cardiac remodeling, analyzing data to improve diagnoses, such as the overdiagnosis of cardiac hypertrophy or dilatation in active individuals.

At present, health systems aren’t able to provide all consumers with devices and a smartphone (required for data tracking and analysis) due to cost and uncertain ROI that depends on wearables effectively and reliably driving behavioral changes. Therefore, the potential for wearables in biomedical research and personalized health remains underexplored at present.

Table 8: Top Fitness Trackers

| Company Product | Function | Feature | Regulatory Guidance |
|---|---|---|---|
| AliveCor KardiaBand/ Mobile | AI Headphones | Records, stores, and transfers single channel ECG rhythms wirelessly through the AliveECG application. | 2015-2017 FDA 510(k) |
| Brain Sentinal | Seizure Detection | Detects the onset of generalized tonic-clonic seizures and provides a warning signal to alert caregivers that a seizure is occurring; placed on the biceps to measure muscle activity through the skin. | 2017 US FDA de novo |
| Everist Health AngioDefender | Diagnosis of CVD | Assesses FMD (Flow Mediated Dilatation) by measuring changes in the brachial artery in response to a temporary occlusion of the artery; measures arteries; ability to widen by using a non-invasive, non-imaging technique based on analysis of pulse waves before and after an increase in blood flow. | Global |
| FitBit | Fitness Tracking | Tracks activity, heart rate, exercise, and sleep stages every day | Global: US FDA 510(k); EU CE Marking |
| iHealth | Wireless Blood Pressure Monitor | Blood pressure and pulse measurement using portable cuff with intelligent display to provide assistance on optimal arm position for precise results, connects with app for smartphones. | Canada MDL; US FDA 510(K); Europe CE Marking |
| Misfit | Patient Monitoring | Tracks steps and distances swum or cycled. | 2012 EU FDA Class II |
| MOCACARE MOCACuff | Wireless Blood Pressure Monitor | Wearable cuff corresponds with the AHA blood pressure categories to monitor changes in blood pressure, alerts on device's interface; synching with smartphone; MOCAheart for heart rate, bloody oxygen, and blood velocity. | No |
| PAI Connect application | Measures PAI Scor: Fitness Tracking | Personal Activity intelligence (PAI) software provides a tracking metric based on heart rate data to manage health and prescribes exercise for optimal health | No |
| Spire Health Tag | Sleep Monitoring | Monitors the stress levels, sleep, heart rate, and breathing pattern; can be placed on clothes, is hypoallergenic and water-resistant. | EU CE Marking |
| Wavelet | Biostrap Wristband (shoe-pod and chest strap HRM) | Provides biometric insights using clinical-quality pulse oximeter. Heart rate, respiratory rate and in-depth sleep tracking synched to phone using cloud-based algorithms to analyze data. | No |

Source: GlobalData



### 4.2.5 Smart Wear/ Clothing

Smart textiles, including smart wear and smart clothing, are wearable garments with integrated sensors, data processing, communication, and power units.

The technology has come a long way from the first well-publicized smart wear in 2000, the Reima Cyberia survival suit, aimed at professionals working in arctic conditions subject to dangerous conditions. Fitted with sensors to monitor the user's metrics, the suit featured sensors tracking heart rate, temperature, humidity, and position. In addition to the electronic functions, the suit was equipped with a user interface to enable the user to take appropriate action if parameters were exceeded. Revolutionary at the time, it was bulky and inefficient. Since then, smart wear and clothing has significantly improved, owing to developments in miniaturization of sensors, more reliable and efficient power and storage capacity. More recently, advances in the ability to free-form print circuit processes enables electronic systems to be assembled directly onto textile items. This type of technology, "e-textiles," will compete for a place among the existing devices that have dominated the market (smartwatches and fitness trackers), as a more discrete alternative to health monitoring.

Innovative products in the space include Sensoria's Smart Sock, designed to reduce fall risk in the elderly populations through improving balance and stability for its wearers. An ongoing neuro-rehabilitation program, StandingTall-PD, uses visual, audio, and sensory cues to help rewire the parts of the brain that control walking in people with Parkinson's while wearing the smart sock. The program aims to prevent freezing-of-gait and falls and to enhance participants' independence. As connectivity improves, the device could send alerts to clinicians who monitor their patients' adherence, activity levels, and gait parameters.

Like other devices, smart clothing is on the cusp of a major transformation. It is likely that in the next 5–10 years, more textile items will enter the market with battery-less sensor networks to continuously monitor a user's health and will disrupt the clothing and electronics sectors, which have traditionally been separate industries.

Table 9: Top Smart Wear/ Clothing

| Company Product | Function | Feature | Regulatory Clearance |
|---|---|---|---|
| Bonbouton | Smart Insole-Diabetes | Monitors the skin's physiological signals to detect early signs of foot ulcers in diabetic patients. | US FDA 510k: ETA 2023 |
| Hexoskin | Smart Clothing for Health Monitoring | ECG & heartbeat monitor, HRV (allowing stress monitoring, effort, load and fatigue assessments), QRS events, and heart rate recovery; breathing rate; activity. | No |
| LifeSense Group | Smartwear for urinary incontinence | Combination of smart textiles, wearable sensors, and tailored exercise programs. | No |
| NeoFect Rapael | Smart Glove for Rehabilitation | Sensor technology acts as variable resistor that changes as the glove is bent; 9-axis movement of 3 acceleration channels, 3 angular rate channels, and 3 magnetic field channels that measure movements for patients recovering from a stroke. | US 510(k); Europe CE Marking |
| NeuroMetrix Quell | Wearable Pain relief | Neurostimulation device for treating chronic pain is lightweight and can be worn during the day while active, and at night while sleeping; advanced sleep tracking. | Regulatory: 2016 CE Marking (93/42/EEC); US FDA 510(k) |
| Owlet Smart Sock | Pulse Oximetry for Infants | Tracks baby's oxygen and heart rate levels during sleep and wirelessly transmits data to a base station via Bluetooth. | US FDA 510(k) |
| Sensoria Smart Moore Balance Brace | Patient Activity | Detects patient adherence along with activity type, activity level, cadence, time on the ground, and gait speed; textile sensors, mobile application, and a cloud infrastructure for data analysis. | US FDA 510(k) |
| Siren Smart Sock | Monitoring - Diabetes | Tracks foot temperature and helps to find potential signs of diabetic foot ulcers; alerts users when inflammation is detected; fabric made with neurofabric and temperature sensors. | US FDA 510(k) |

Source: GlobalData

### 4.2.6 Skin Patches

Skin patches are thin, soft, adhesive patches containing electronic systems that stick onto skin. They can be battery or non-battery powered, reusable or disposable, and provide information such as the wearer's blood pH, sweat rate, and blood chemistry including levels of chloride, glucose, lactate, and more. Wearing skin patches enables faster diagnosis of medical problems, where electrolyte and other chemistry abnormalities could in signal early warning signs of chronic diseases such as cystic fibrosis, diabetes or a lack of oxygen. In addition, these data can help track treatment progress for other diseases, where doctors can monitor patient's recovery remotely and intervene when necessary, while enabling "seamless" and discrete wear, which is a common area of need preventing advancement of many wearable technologies.

To date, electronic skin sensors, or biointegrated sensors, can track biophysical signals including heart parameters, breathing, temperature, and motion, predominantly used for diabetes management and cardiovascular monitoring. Patches can be placed directly on the skin in the location required for optimal, consistent, and stable data collection—for example, on the chest next to the heart for measuring heart rate. A second generation of sensors, facilitated by more efficient processing, energy usage, and communication is expanding the market for skin patches. As a result, more advanced systems are emerging that can track specific biomarkers and physical actions such swallowing to speech.

Commercialization of wearable skin patches requires an interdisciplinary approach, with funding from government, corporate investments and charitable foundations an essential starting point. Before skin patches reach the wider consumer base, technical challenges include overcoming issues with adhesive degradation, miniaturization of imaging and spectroscopy, materials and design, data type and interpretation, and patient/ consumer behavior. Given more time for validation, regulation, and data protection, along with improvement in manufacturing processes assuring higher yields and lower costs, skin patches are expected to revolutionize remote patient monitoring across every aspect of medicine.

Table 10: Top Skin Patches

| Company Product | Function | Features | Regulatory Clearance |
|---|---|---|---|
| Biolinq | CGM | Intelligent Continuous Glucose Monitoring System is a needle free, wearable system intended for continuous glucose monitoring. It is designed to continuously monitor glucose levels by placing the sensor onto the skin. It is based on Micro-Array Technology. | FDA 510(k) ETA 2022 |
| BioTelemetry | ePatch for CVD monitoring with ECG | Patch and sensor Technology incorporates detection capability into a lightweight, easy-to-use patch sensor. It adheres to the skin and is easily read out to a PC via a USB interface cable; the cardiac monitor is intended for cardiovascular monitoring. | E02018 FDA 510(k) (K171410); CE Mark |
| Eccrine Systems | Remote Patient Monitoring: Depression, CGM, Infectious Disease, Diabetes | Monitors sweat biomarkers; sends the data to a remote system through a transceiver. Sensors and arrays analyze sweat rate and other biomarkers. It features proprietary sensors, data processors, and management systems that can detect and manage sweat-sensor data including real-time data of glucose levels by absorbing sweat from a porous material. | FDA 510(k) ETA: 2023 |
| Epicore Biosystems: Sweat Sensor | Remote Patient Monitoring: Sweat Analysis | Non-invasive, skin-like wearable fluidic sensor that is designed to measure prognostic biomarkers in real time, characterize skin hydration, and monitor patient response. It helps healthcare professionals to provide personalized treatment regimens for patients. It is capable of analyzing small droplets of sweat directly from the skin. | FDA 510(k) ETA 2024 |
| Gentag | Diabetes Monitoring, Glucose Monitoring Patch | Pain-free diabetes monitoring patch is a smartphone-based diabetes patch intended for type II diabetes management. It is designed to facilitate pain-free measurement of glucose levels using tiny wireless battery-less glucose sensors placed on the skin. | FDA 510(k) |
| iRhythm | CGM and ECG | Water-resistant, single-use, wearable electrocardiogram patch intended for cardiovascular monitoring; data is sent to iRhythm's clinical app, which relies on algorithms to deliver results. | FDA 510(k); CE Marking |
| Kenzen | Health Monitoring | Sensors continuously monitor sweat, heart rate, and body temperature; sensing platform linked by custom algorithms via a companion mobile app that provides contextual insights about an individual's body when they are at work (under extreme conditions). | No |
| Medtronic Enlite Sensor | CGM Patch- diabetes | Guardia 2 Link transmitter uses Enlite glucose sensors to power the SmartGuard "suspend before low" feature within the MiniMed 640G insulin pump. | CE Mark |
| Nemaura | My SugarBEAT patch: Diabetes | Draws a small amount of selected molecules, such as glucose, into a patch placed on the skin for diabetes (glucose monitoring) and intensive care (glucose monitoring and oxygen depletion). | Approved |
| PKvitality | Diabetes Management, Glucose Monitoring | SkinTaste Technology patch equipped with K'apsul which contains biosensors to test glucose levels when it comes into contact with the skin. It inserts tiny micro-needles into the skin to probe interstitial fluid. | CE Mark ETA 2022 |
| Theranica Nerivio Migra | Pain relief- migraine | Single non-invasive unit composed of ENS/NMES electrodes, a safe, low-powered battery, and a smart chip; Maximum Effectiveness (ME) mechanism collects and evaluates EMG (Electromyography) signals from the treated muscle, as a response to the stimulation; information is processed in a chip, providing guidelines to optimally adjust the location of the electrodes and/or the level of the stimulation intensity in order to maximize muscle stimulation efficiency to reduce migraine pain. | FDA de novo ETA 2019; CE Mark ETA 2021 |
| Vista Solutions | Real-time Patient Monitoring | VitalPatch biosensor signal processing capability and a set of biometric software algorithms that enable it to read, monitor, and sense the patient’s vital signs provided by VitalPatch on a continuous basis. | 2018 FDA 510(k) |
| VivaLNK | Human Vitals Monitor: ECG and heart rate | eTechnology wireless, waterproof, multi-sensor, flexible, electronic circuit patch intended for stress and physical health monitoring; attached to chest with medical grade adhesives (72 hour use before recharging its battery); alerts Scout mobile app to notify when stress levels are high; body, sleep quality, tension and stress levels are measured by monitoring heart rate variability. | 2019 FDA 510(k) |

Source: GlobalData

### 4.2.7 Diagnostic and Therapeutic Wearable Devices

In terms of device, the global market has been classified into monitoring devices and diagnostic devices (including FitBit, Omron, Nemaura, and MC10) and therapeutic devices (such as the Medtronic MiniMed Insulin Pump). Diagnostic and monitoring devices are further segmented into vital signs monitoring devices, glucose monitoring devices, sleep monitoring devices, fetal monitoring and obstetric devices, and neuromonitoring devices. While therapeutic devices can be categorized into pain management devices, rehabilitation devices, insulin pumps, and respiratory therapy devices, which provide RPM and therapeutic delivery.

# 5 Industry Analysis

Wearable OEMs are increasingly exploring the healthcare sector, primarily to exploit patient-generated data and to promote preventive healthcare. Apple Watch's ECG capability, Samsung Watch Active's blood-pressure monitoring feature, and the Fitbit-Google partnership to connect patient-generated health data with patient medical records are some of the recent examples of how the tech leaders are positioning their offerings in the lucrative healthcare industry. As reported in Q1 2019 results, Fitbit's Health Solutions business grew nearly 70% and garnered revenue of $30.5M.

Many start-up firms worldwide are evaluating techniques to refurbish and augment wearable healthcare technologies that can be used to amplify connectivity between the consumers and healthcare professionals. In addition to wrist-worn devices, implantable devices and ingestible sensor-embedded pills are also emerging in the healthcare sector. In November 2017, the FDA approved the Abilify MyCite pill—an antipsychotic used to treat schizophrenia and bipolar disorder—which tracks a patient's adherence and transmits the message to a wearable patch. The patch then transmits the information to a mobile app. Eventually, wearable devices will drive replacement of some complex medical procedures: Apple Watch is poised to lessen the use and demand for large ECG machines. However, health data related technological improvements will also call for stricter regulations, which will noticeably reduce the operating flexibilities of wearables OEMs.

## 5.1 Traditional Definition of a Wearable Technology Device

Wearables are one of the fastest growing themes in the global technology landscape. Traditionally, in simple and broad terms, the definition of wearable technology embraces multiple items including electronics, mechanical technologies, and functional materials that are worn on or attached to the body. This can encompass electronic technologies including products such as smart or advanced materials used in clothing, equipment, or devices. Generally, wearables are considered to be noninvasive and autonomous. With respect to healthcare, wearable technologies perform a particular medical function, be it support or monitoring, over a prolonged time period. At present, medical-grade wearable tech in healthcare considered diagnostic or therapeutic is limited to few players. The increasing integration of wearable technologies with IoT, big data, AI, and cloud computing solutions is enabling faster and deeper penetration of the wearable gadgets into the connected-society. While wearables are steadily gaining prominence in consumer markets, they also exhibit potential to optimize enterprise operations with extensive scalable usability in diverse industries.

## 5.2 Key Opinion Leader Definition of Wearable Tech

KOLs from across the US and Europe were interviewed by GlobalData for this report. These experts provided insights that captured the overarching sentiments within the Digital Health field and also highlighted issues unique to therapy areas and device types across each geographical market. Overall, KOLs were happy with the current outlook for digital health and wearable technology in healthcare, viewing wearables as a key growth area with huge potential to improve all aspects of healthcare, although some called into question the definitions and current classification of wearables.

*"A wearable itself is any device that the patient keeps on their own body that is going to be used to monitor some aspect of the patient's overall health or well-being. But I think, in that group of devices, I also like to include sensors."*

US Key Opinion Leader

*"I'm really enthusiastic about the potential of wearable health sensors in general. Because what health sensors do, in this case, is that it makes patients the point of care."*

EU Key Opinion Leader

*"It's like your guardian angel. Because you don't know it's there... But you know, but when it's there, suddenly you receive the help that you need, without even noticing that you needed it… I find most technologies are too interventionist, and therefore annoying."*

EU Key Opinion Leader

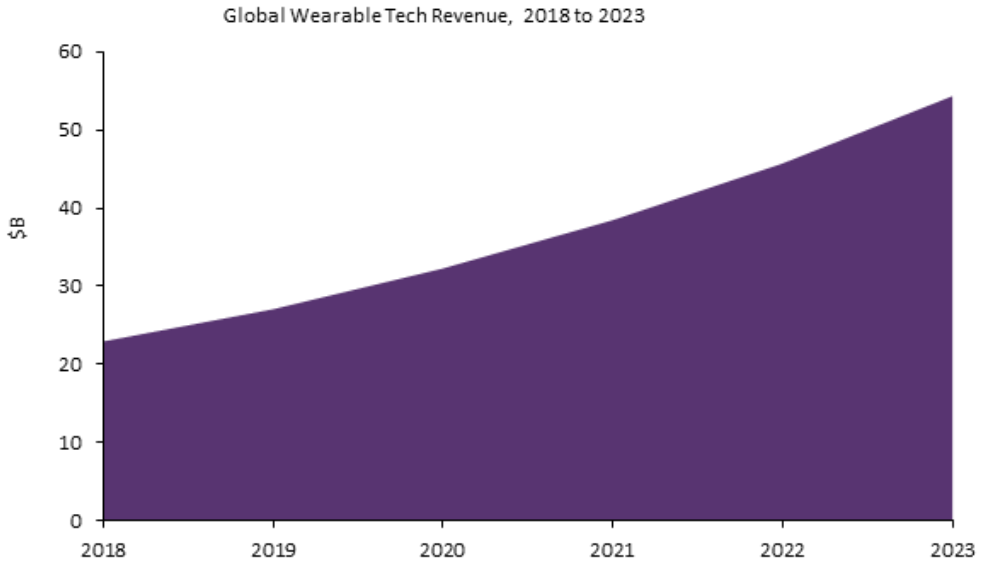
*"It's always on thin ice when I hear the word 'wearable.' I understand that's how this whole trend came mainstream that wearables are becoming available by the tens of millions. But now, 'wearable' is a misleading term because all the sensors that we're designing to be wearables might not be wearable at all, such as an RFID microchip implant is something I can wear under my skin, but it's implanted, for instance implantable or wearables."*

EU Key Opinion Leader

## 5.3 Market Size and Growth Forecasts

The wearable technology sector will grow from $22.9B in 2018 to $54.4B in 2023, expanding at a CAGR of 19%. GlobalData sees smartwatches as representing the largest and fastest growing segment in the wearable tech market over the forecast period, followed by fitness trackers.

Figure 3: Wearable Technologies Revenue to Grow More than Double Within Five Years

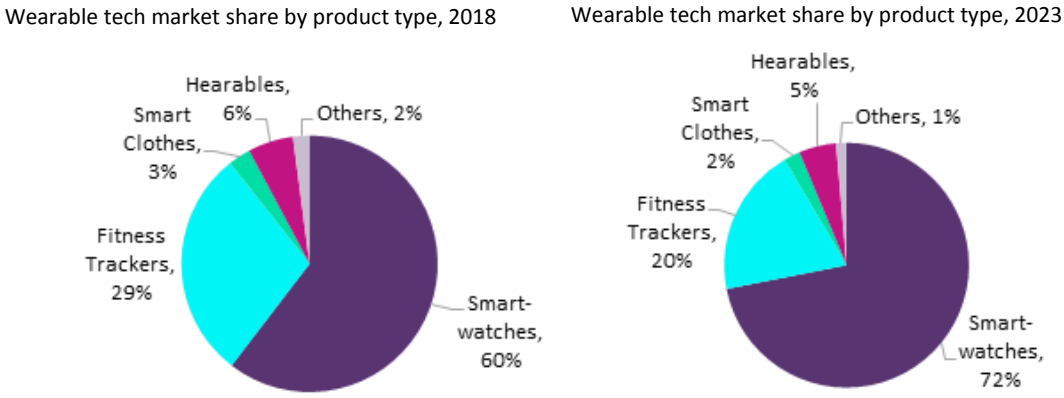



Source: GlobalData



The smartwatches segment accounted for a 60% global share in the wearable tech market in 2018, powered by demand for Apple Watches and rapid penetration of brands such as Xiaomi, Huawei, Garmin, and Samsung. The segment is foreseen to hold 72% in 2023. Fitness trackers accounted for nearly 29% of the market in 2018, attributed to the performance of brands such as Fitbit, Garmin, and Huawei. The segment is anticipated to witness a decline in market share and settle at 20% in 2023.

Figure 4: Smartwatches to Witness Steady Increase in Market Share Between 2018 and 2023




Source: GlobalData



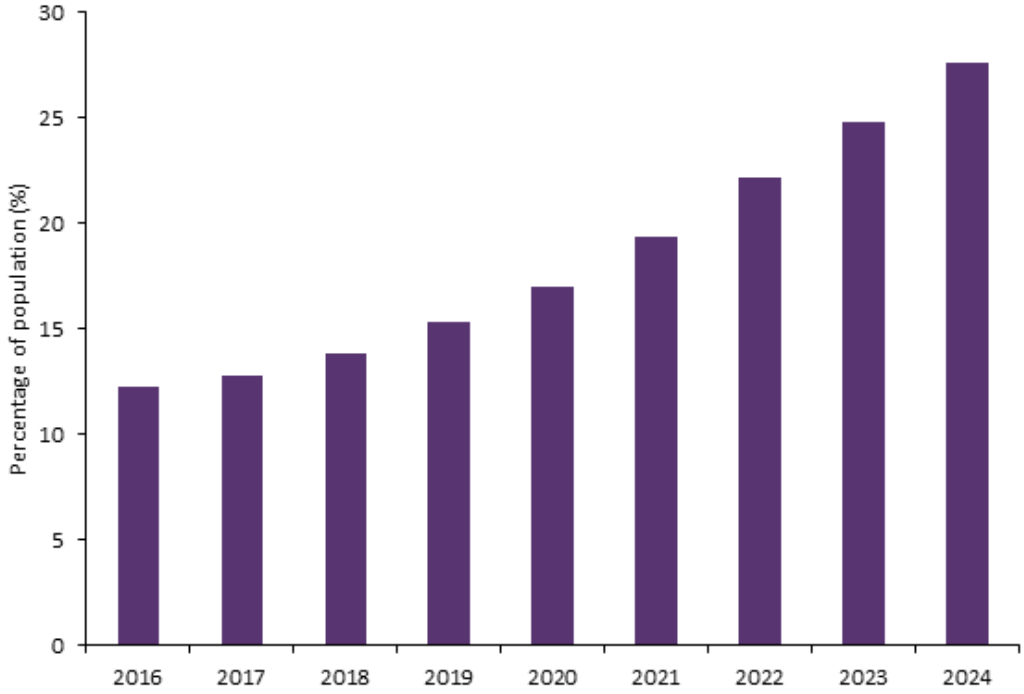
## 5.4 Smartwatches are the Leaders of Wearable Technologies, Followed by Fitness Trackers

The smartwatches segment is anticipated to grow from $13.9B in 2018 to $39.1B in 2023, expanding at a CAGR of 23% between 2018 and 2023. The soaring popularity of smartwatches is entirely attributed to the perceived convenience and value they provide to the consumers. Smartwatches are progressively heading towards becoming “one-stop” solutions featuring cellular connectivity and covering an array of activities such as health monitoring, health coaching, contactless payment, and gaming, among many others. The fitness trackers segment is forecast to grow at a CAGR of 10% between 2018 and 2023 to reach $10.7B in 2023, from $6.6B in 2018. Although fitness trackers are experiencing a slowdown in market adoption, especially in developed countries, the emerging economies are providing newer impetus for this market’s future sustenance.

*“People have had pedometers for years, but once people started having digital pedometers sort of in the mid-2000s that came out when you wore it on their waist, for instance, that was widely available, people then first started to realize that you could have a widespread use of these trackers to help people monitor their fitness. But it was many years later, as far as I can tell, and still it's not widespread that people are considering using these things for actual healthcare. There's still a general fear or skepticism about the use of these consumer wearables for health.”*

US Key Opinion Leader

## Figure 5: Smartwatch Ownership is Expected to Increase

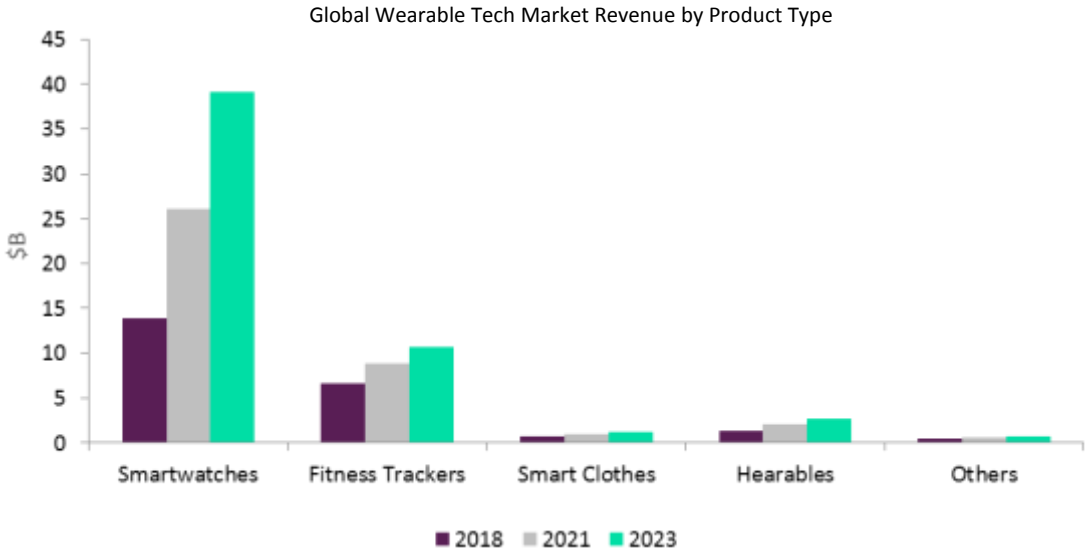



Source: GlobalData

## 5.5 Hearables Represent a Larger Market Size, While Smart Clothes Witness Faster Adoption

The growth of the hearables segment can be mostly attributed to the performance of Apple AirPods. The "off-the-charts" demand for Apple AirPods took Apple CEO Tim Cook by surprise, who called AirPods a "cultural phenomenon." Samsung, Google, and Huawei also witnessed steady growth in the hearables segment in 2018. Supported by the ripening competition among audio companies, tech dynamos, and start-up firms, hearables are experiencing faster development and deeper market penetration. The segment is anticipated to grow from $1.3B in 2018 to $2.7B in 2023 at a CAGR of 15% between 2018 and 2023. Despite impressive growth, smart clothes are still a nascent segment and have yet to attract substantial investment from tech giants. Google and Samsung are the only two big names involved in the smart clothes segmental development. Smart clothes are set to expand from $650M in 2018 to $1.2B in 2023 at a CAGR of 12%.

Figure 6: Smartwatches and Fitness Trackers to Propel Wearable Tech Revenue




Source: GlobalData



## 5.6 Outside Smartwatches and Fitness Trackers: Other Wearables as Medical Devices

A number of small start-up companies are entering the market by focusing solely on the development of wearables for specific medical purposes. These devices are part of the "others" segment of wearables (outside smartwatches, fitness trackers, hearables and smart clothes) that also includes wearable cameras, jewelry, and more. This segment is poised to grow at a CAGR of 10% between 2018 and 2023, thus marking revenues of $758M in 2023, compared to $478M in 2018.

Wearable devices made specifically for medical purposes can be grouped into device types based on the type of medical issue they treat. The three primary areas currently being targeted by wearables are cardiology, diabetes and neurology.

### 5.6.1 Cardiology Wearables

Cardiac health is a high-profile issue, with almost half of Americans (47%) having at least one of three major risk factors for heart disease (Fryar *et al.*, 2012). Such a key medical need has driven production of more cardiology-related functions for wearables, such as heart rate tracking, and many companies are looking to expand their cardiology offerings. This includes large players like Apple who are incorporating improved heart rate monitoring systems into their existing smartwatches, as well as smaller players like AliveCor who are manufacturing devices specifically for mobile, patient-focused ECG measurements.

### 5.6.2 Diabetes Wearables

Diabetes is one of the most common endocrine diseases. According to GlobalData, there are 193,653,147 people over the age of 20 diagnosed with Type 2 Diabetes across the 16 major markets in 2019, and this number will grow at an Annual Growth Rate of 4.89% to reach an estimated 252,076,912 cases by 2026. People with diabetes are constantly concerned with tracking and managing their glucose levels. The development of CGM sensors, wearable minimally invasive devices, has modernized glucose monitoring in recent years. People with diabetes are able to wear a small patch for several consecutive days, preventing the need to self-monitor using finger prick measurements. CGM sensors have typically been aimed towards people with type 1 diabetes; however, they represent only 5–10% of total diabetics since the majority of people with diabetes have type 2 (Healthline, 2017). There is therefore huge market potential still available for development of CGMs for type 2 diabetics, as well as targeting the pre-diabetic market and potential non-diabetics taking part in wellness or fitness programs.

*“Diabetes is the absolute top example because of how proactive patients are, how advanced technologies are in their cases, from the artificial pancreas to blood, to needle-less blood glucose monitors to have long-term management they need, and how easily the data they measured with the devices can be quantified even without the help of a medical professional.”*

EU Key Opinion Leader

### 5.6.3 Neurology Wearables

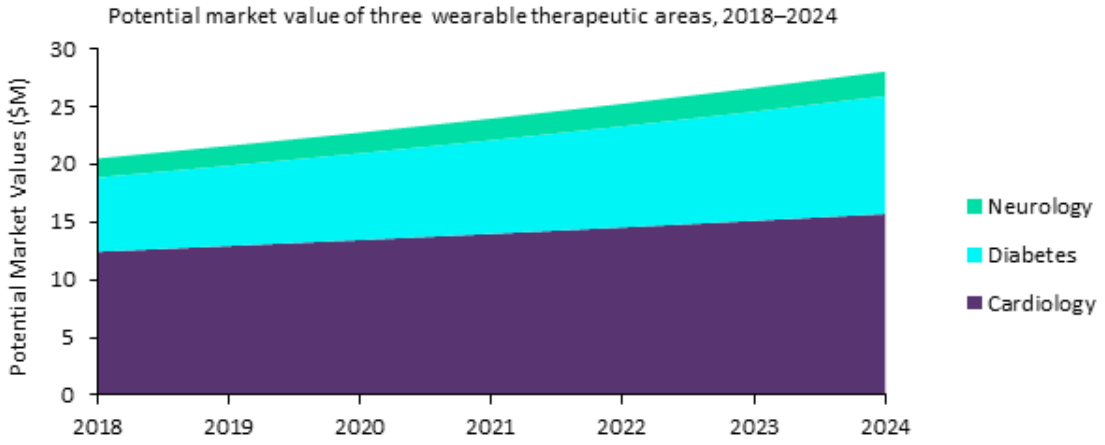
According to the Global Burden of Disease 2016 Neurology Collaborators, neurological disorders are the second leading cause of death globally, second only to heart disease. In 2017, approximately a third of the total population suffered from neurological diseases such as Alzheimer's, multiple sclerosis, 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.

*"So, if you talk about disease management, a Parkinson's disease patient at the beginning, they are treated with physiotherapy and advice. You try to avoid medication as much as possible because medications always have some side effects. But there is a point at which you need to do the transition between your therapy and actually start having medication. And that point is crucial. So what happens with many patients because of their age, social circle, or social-economic circumstances, it's not entirely obvious to the clinicians when that transition happens, and a patient might go quite a significant amount of time without having the right medication, or even without having the right amount of medication, the right dosage, et cetera. Because that's the other part, that once you decide that you need to transition to a medication, the pharmacotherapy, you need to experiment with different drugs to find out what drug is more effective, and has a better fit in your case. And then even more about management with a particular disease is whether you have taken your medication or not, because when drugs are not switches that are 'on' and 'off.' A drug has a period of absorption, then it has a plateau, and then it has a period in which it diminishes in effect. So you have to control this. And certainly, definitely, mobile devices will have a role to play… You can raise the alarm to the clinician to assess this patient, because it's very likely that he requires a transition to pharmacotherapy... Mostly dementia patients will have devices that will help them, you know, manage their medication more effectively."*

US Key Opinion Leader

The graph below depicts the market potential for apps related to wearables in the cardiology, diabetes, neurology, and other therapy areas.

Figure 7: The Market Potential for Apps Connected to Medical Wearables Is Increasing

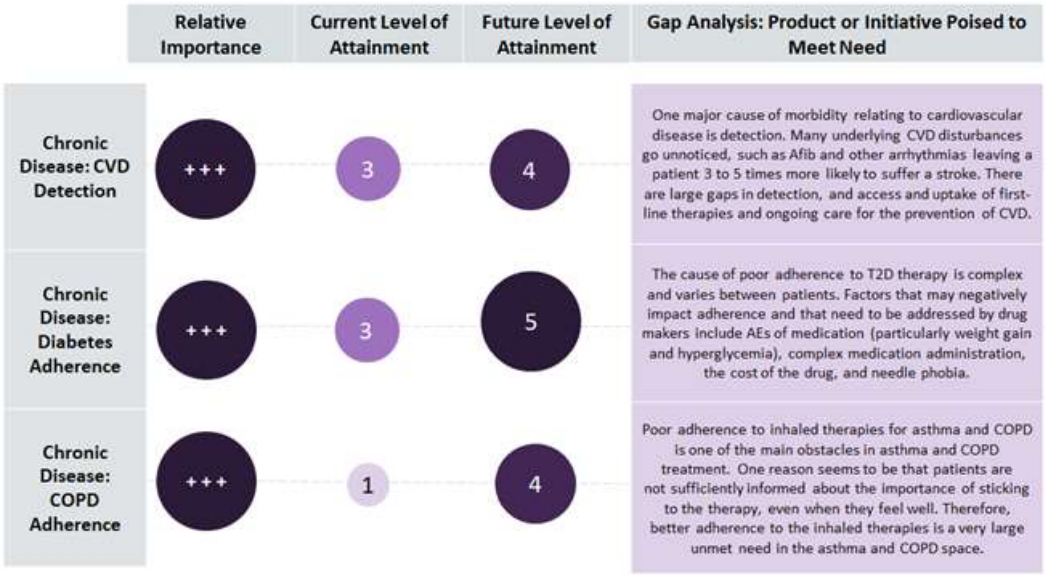



Source: GlobalData

### 5.6.4 Unmet Needs

Key opinion leaders offered their opinions on the impact of wearable technologies across disease areas where there are current unmet needs, with Figure 8 and 9 detailing relative importance, current level of attainment, future level of attainment, and gap analysis. Notably, there is a large gap in chronic disease with a high level of future attainment, while prehabilitation and female health are moderately important in terms of current burden of chronic disease across aging populations.

Figure 8: Unmet Needs




Source: GlobalData
AE = adverse effect; COPD = chronic obstructive pulmonary disease



**Chronic Diseases**

*"Diabetes and chronic obstructive pulmonary disease, COPD, there are a number of devices out there that monitor sleep apnea, COPD, measuring oxygen saturation, measuring the frequency or the quality of the breathing, for example. There are devices that are monitoring falls on the patient. There are devices that are monitoring dysrhythmias. So if you think about wellness in general or even the obesity epidemic, the devices that monitor and coach the patient to be more active, for example. It will be a wide field and several numbers of medical conditions or aspects that you can think are definitely going to be…are being impacted right now. I think cardiac disease, diabetes and pulmonary diseases like COPD are probably the main area with unmet needs."*

US Key Opinion Leader

**Chronic Pain Management**

*"Wearables to deal with chronic pain to measure pain. There are so many physiological and biochemical markers of being in pain. But you could imagine the equivalent of PCA [patient-controlled analgesia] but I think that there will be huge regulatory problems with that, so it will be like self-prescribing. I think that patients with chronic pain should be able to self-prescribe on the whole. Wearables could really enable that area of medicine to be improved."*

EU Key Opinion Leader

**Prehabilitation**

*"One area to mention specifically is prehabilitiation. Say in one month's time, a person coming in for major operation. Give them a wearable which sends reminders and they have to be as fit as they can be, helps train them, et cetera. It's an interesting area of medicine, only recently been acknowledged, but improves outcomes enormously."*

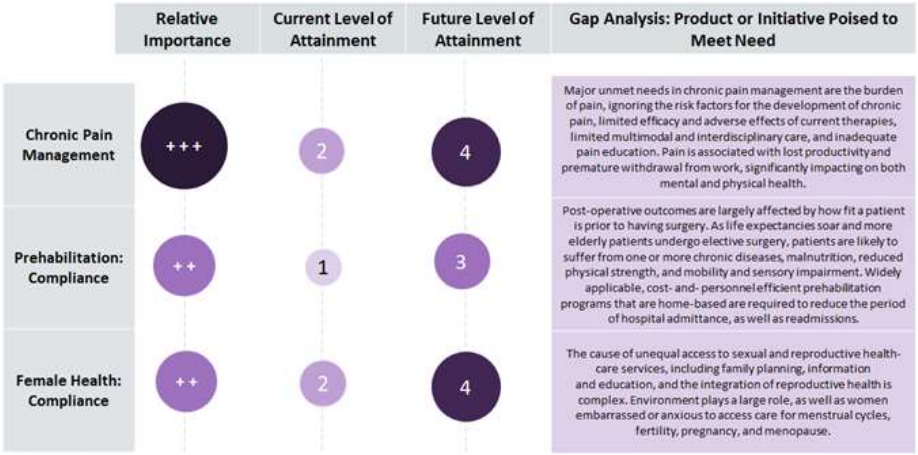
EU Key Opinion Leader

**Female Health**

*"The whole of female reproductive years are so interesting and proprieties change so much. Fertility hasn't been neglected; there are good test kits and things to be done at home. Pregnancy itself, there is a lot more monitoring that could be done at home. There's no real reason why a woman shouldn't be able to monitor her baby at home. No real reason why one couldn't have a remote fetal monitor which was Bluetoothed into the hospital, and instead of having to come in [and] leave children with friends or family. The fetal heart beat trace, the CTG [cardiotocograph], there is no reason at all why that shouldn't be done at home, and probably not at huge expense. I see the CTG and heart beat traces of all the patients on my unit on a central monitoring system. Why can't all those patients, especially with reduced movements, be provided with something they have strapped to their tummy without them having to go anywhere. They would feel very safe and secure and wouldn't have to, say, drive their cars."*

EU Key Opinion Leader

Figure 9: Unmet Needs




Source: GlobalData



## 5.7 Market Drivers

A number of the current trends occurring in healthcare are driving the use of wearables. Many of these trends come from the patient side, such as a growing population of technology users, growing popularity of health and wellness, and an increased demand for patient-centered care. From the physician side, the trends include big data as well as treating patients using personalized, preventative care are also increasing demand for wearables. Macroeconomically, the aging population and emerging markets are the main market drivers.

### 5.7.1 The Aging Population

The proportion of the elderly is growing in almost every country, mainly due to increased life expectancy as healthcare and living conditions continue to improve worldwide. The United Nations has described this phenomenon as one of the most significant social transformations of the 21st century. As populations age, there is an increased burden on healthcare systems, more complex needs and chronic diseases, and a greater need for diagnosis and prevention and rehabilitation during and after hospitalization.

*"Being able to know a patient's baseline activity and then be able to monitor that after they've had surgery, or chemotherapy, or after a procedure, being able to align their GPS data with their staff data and be able to know exactly, you know, how active they are, and then, relate that back to some sort of quality-of-life measure, I think that's going to be absolutely essential."*

US Key Opinion Leader

*"If we look, for instance, in the NHS in the UK, the largest proportion of an insurance expenditure is invested in chronic patients with long-term conditions, where one of the factors that drives that expenditure is that these patients need constant monitoring on the basic healthcare facilities, regularly. So certainly, a mobile device presents us with a huge opportunity so we can detect when intervention with a patient is actually required, when for instance, a patient can be referred, or when this patient can be managed for particular types of services, for instance some local services or just a patient can be managed by itself. This provides tremendous amount of reassurance to the patient."*

EU Key Opinion Leader

### 5.7.2 Focus on Patient-Centered Care

Patient-centered care has emerged as a principal approach to healthcare, as healthcare professionals aim to emphasize partnerships with patients throughout their treatment course. Wearable technologies enable this relationship by placing knowledge and control back in the hands of the patient. Patients can use wearables to measure and track their own health metrics and are empowered to bring this information to their physicians to help guide a treatment plan. Continued focus on patient-centered care will bolster wearable use as patients continue to take control of their own health.

### 5.7.3 Growing Popularity of Health and Wellness

Known as the "wellness trend," modern day living has come to incorporate a serious awareness of health and fitness. This is evident in multiple industries, as brands focus on healthy eating, organic products, and spiritual well-being. With ever-increasing connections to smartphones, more and more people are using mobile apps for health and fitness, and many of these are connected to wearables with sensors for biometric tracking. As more apps are developed, wearables are able to perform more functions, driving increased demand.

### 5.7.4 The Trend Towards Personalized Preventative Care

Following the wellness trend, there is a growing societal emphasis on personal health management. People tend to become engaged in their own health before they even become patients, with a focus of preventing any health problems that could potentially arise. Wearables give users the ability to precisely measure and interpret their own individual health data, empowering them to play a more significant role in their own healthcare.

### 5.7.5 Growing Population of Technology Users

The emerging generation, sometimes known as "Generation Hashtag," is the instant messaging generation, naturally attuned to virtual communication. These digital natives are innately connected and seeking to connect via online environments, not only for work but also for socializing, finances, entertainment, and increasingly, their healthcare. Generation Hashtag is very open to the idea of staying connected through wearables and will be some of the first consumers of new wearable technology when it emerges.

### 5.7.6 Improving Technology

The miniaturization of sensor technologies combined with "big data" analysis tools, AI, and ML, has allowed wearable technology to be developed. Investments from large technology companies like Apple and Google (Alphabet) are constantly driving improvement of these technologies, leading to better and better wearables. As technology continues to improve, wearables will offer more and more functions and consumers will be increasingly driven to purchase them.

### 5.7.7 Focus on Big Data

"Big data" is a term that describes an extremely large volume of data. When properly analyzed, big data can be very powerful in providing insights for business strategy and, importantly, healthcare. Wearables are a key tool in collecting large amounts of data and can easily be paired with software systems for analysis. Big tech companies like Google (Alphabet) are developing algorithms that interpret large collections of data from wearable sensors, and these interpretations can be used to develop AI programs to automate many healthcare functions, from diagnosis of medical problems to interpretation of ECG readings and more. The trend towards big data sets will inherently drive wearable use to help provide these data sets. See our Thematic Report *Big Data in Healthcare* (GDHCTR002).

### 5.7.8 Emerging Markets

Emerging markets are providing a large amount of growing demand for wearables. Markets such as Asia Pacific (excluding Japan), Central and Eastern Europe, Latin America, and the Middle East and Africa are beginning to use more and more wearables as their healthcare infrastructures improve and their access to technology increases. Within Asia Pacific, China will experience the largest growth given its ongoing economic, population and technological advancements, and a population that is continually commanding more and more disposable income. Additionally, Chinese technology companies are entering the wearables market and driving local demand further. As the demand in developed markets turns to more complex wearables, these emerging markets will continue to drive basic wearable demand.

*"I don't think there is any question whether valuables have a huge potential in healthcare. The question is not whether they have, the question is how we can make it happen, how regulatory… how policymakers can make it happen, how companies can develop the right technologies for these patients, and how these patients can be motivated to get involved in developing technologies from the companies."*

EU Key Opinion Leader

## 5.8 Market Barriers

Just as certain trends are driving the healthcare wearables market forward, a number of factors are inhibiting the market. From the patient side, the high cost of wearables, difficulty in getting them reimbursed, and concerns over privacy are all barriers to wearable use. Physicians are less likely to suggest use of wearables due to a perception of poor quality of data, as well as a lack of clinical evidence supporting them. Finally, regulation slows down the pace of innovation in the wearables market.

### 5.8.1 High Cost of Wearables

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 and often much higher, is a barrier to a large portion of the population. Unless prices decrease or reimbursement structures change, many consumers will not be able to afford most wearable devices.

### 5.8.2 Reimbursement Challenges

In many countries, reimbursement is difficult to navigate, often with lengthy processes and unclear requirements. Reimbursement and payment for wearables are still not widely adopted worldwide. Given the high price of wearables, this limits the number of consumers who have access to them since not many people can afford to buy them without reimbursement.

### 5.8.3 Perception of Poor Data Quality

With more and more wearables entering the market, it can become hard to differentiate between those that generate good quality data and those that generate poor quality data. As a result, there is a perception among physicians that data generated from wearables is of poor quality and is not trustworthy. Physicians are thus discouraged from following through with clinical action based on this data. In order to circumvent this issue, wearables can prove their efficacy by registering with a regulatory body such as the FDA, or by publishing solid clinical trial results proving the data quality of their device.

*"How good is the data that is collected from these mobile sensors? The standard sensor, if we look at the current figure of quality of the sensor, the error in measurement with these sensors is about 20%. Meaning that if a sensor tells you 100, you are anywhere between 92 and 118… So, you have to wonder when you develop technology, how good an advice you can give when you know that on the sensor side, the signal itself can have a given amount of, let's say, noise or error."*

EU Key Opinion Leader

*"And then also, from the field of view of the patients, the clinicians and the patients, that when they receive advice of all sorts from the device and the software that makes recommendations, then they are able to ground their choices on realistic information and not taking the device, for instance, as a ground truth, because it might not be. So when you develop a system, and I am looking at this as an example end to end, there are challenges at every stage that need to be addressed. And this is currently one of the big areas that both engineers, clinicians, machine learning guys are looking at."*

EU Key Opinion Leader

### 5.8.4 Lack of Clinical Evidence Supporting Many Wearables

Many wearable manufacturers, especially those of smartwatches, have not put their devices through the rigors of clinical trial testing. Physicians, who are trained to require evidence to guide treatment decisions, are often reluctant to trust new therapeutics, including wearables, without evidence backing up their safety and efficacy. Some companies are excelling at

clinical testing of their devices; for example, AliveCor has run extensive clinical tests on its KardiaMobile algorithm to detect atrial fibrillation. Other wearable manufacturers will gain more trust from physicians if they follow suit and are able to showcase solid clinical evidence behind their devices.

### 5.8.5 Regulation Slows Down the Pace of Innovation

Approval by regulatory bodies such as the FDA is often a lengthy process. The FDA's traditional approach to regulation of medical devices is especially lengthy and can often take years before a product reaches the market. Although the FDA is currently reviewing and changing its approach to digital therapeutics including wearables, the process is still daunting for many manufacturers, especially technology companies such as Apple or Garmin that are entering the healthcare sector for the first time with their wearable devices and have not had much previous experience with the FDA. The FDA is currently in the process of streamlining their regulation protocols for digital therapeutics including wearables, which will alleviate this barrier.

### 5.8.6 Privacy Concerns

With the collection of personal health data comes concern over the privacy of that data. Users of wearables are concerned about the ownership of their personal health data and are concerned about it being used by third parties without their approval. In addition, since wearables often house collected data using cloud storage systems, they can be vulnerable to cyberattack. Wearables manufacturers should invest in cybersecurity and ensure solid data protection procedures are in place to reduce this barrier.

### 5.8.7 Technology Barriers

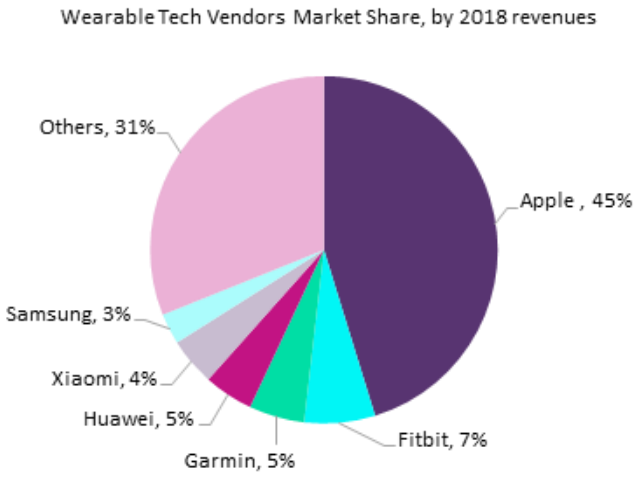
*"When people upgrade their OS, or get a new device, or their space fills up on their phone, I think, you know, you always have to be ready for some technology issues. You can't have an app that's going to work on, you know, 20 different versions of Android and iOS, you have to have at least common denominator. So there's been some technology challenges. But I've been actually pretty surprised at how the vast majority of research subjects are just able to get on the platform and enjoy using it. Even across all demographics, you know, even older patients that we might not assumed to have smartphones have been very welcoming of the technology and the chance to use it."*

US Key Opinion Leader

## 5.9 Competitive Analysis

With low barriers to entry and an enormously wide spectrum of applications, competition in the wearables market is on a continuous rise. With global share of 45% in 2018, Apple led the global wearables market. Apple's brand value, dedicated clientele, and constant emphasis on innovative services that add value to consumers contributed to its success. Fitbit held a 7% share by the end of 2018. The company's fitness trackers segment caused a major slump in its revenues that year, but its smartwatches performed well in matured markets. Fitbit demonstrated an aggressive market approach in 2018 and its total shipments witnessed a leap of 1,000%+ compared to 2017. Fitbit's smartwatches contributed 44% of the company's revenue in 2018 as compared to just 8% in 2017. Xiaomi held a 4% market share in 2018, solely credited to its ability to deliver competitive technological products at substantially lower prices. Garmin and Huawei both accounted for 5% of the market in 2018. Garmin's broad product portfolio, established client base and increasing focus on smartwatches enabled it to succeed in the market, while Huawei's growth is attributed to its strong command in China and improving prominence of Huawei wearables in Europe and Asia Pacific. Samsung also gained traction and held a 3% market share in 2018.

Figure 10: The Top Five Companies Collectively Commanded Almost 70% of the Global Wearables Market in 2018




Source: GlobalData



While three American firms—Apple, Fitbit and Garmin—cumulatively held over half of the wearables market, Chinese firms Xiaomi and Huawei are striving for deeper penetration in the fast developing markets, building on strong foundations in their domestic market. The following chart demonstrates the position of leading firms across different geographies.

Figure 11: Apple Are Leaders Across Multiple Geographies


Source: GlobalData



## 5.10 Deals: Mergers and Acquisitions

Tech acquisition remains the principal rationale for consolidations in the evolving wearables market. Although limited, but over the past four years, leading players engaged in consolidation to boost their ongoing initiatives or to diversify into new segments. Some of the notable consolidations include Fitbit's 2016 acquisition of Pebble Technologies for diversification into smartwatches, followed by its acquisition of Twine Health to expand its offerings to health plans, health systems, and self-insured employers. Other tech M&A include Apple's 2018 acquisition of Akonia Holographics for development of smart glasses, and Google's 2019 purchase of Fossil's smartwatch technology for enhancement of its smartwatch competencies. Alongside the incumbents, startup firms are also engaging in consolidation activities: Magic Leap acquired Israeli cybersecurity company NorthBit in 2016 and the 3D division of Swiss computer vision company Dacuda in 2018.

Funding activities have maintained a steady progression. Magic Leap generated a total of > $2.5B in funding since inception. Digital health M&A activity has remained consistent in the first half of 2019, in line with increasing number and value of acquisition, as well as the high-profile nature of those involved. In 2018 there were over 50 digital health M&As with disclosed value of $7.6B with players such as Roche acquiring Flatiron Health for over $1.9B as part of its wider expansion in the digital arena, and SleepsScore Labs acquired Sleep.ai, a company specializing in wearables and apps for sleep tracking.

Similarly, partnerships are also surging: Garmin partnered with Fitbase to offer new data management for wearable-based research, Eisai formed an alliance with wearable tech leader Empatica for the development of the Embrace 2 intended for epilepsy patients, while tech also stepped up to the health market with both Samsung and Google Cloud forming alliances with Insulet and Infosys, respectively.

The table below exhibits the key M&A transactions involving wearable tech companies over the past four years. The key M&A rationale in the theme is product types like smartwatches, smart glasses, and hearables.

Table 11: Tech M&A

| Announced Date | Acquirer | Target | Value $M | M&A Rationale |
|---|---|---|---|---|
| Jan. 2019 | Google | Fossil | 40 | Smartwatch technology |
| Aug. 2018 | Apple | Akonia Holographics | Undisclosed | AR smart glasses technology |
| Jul. 2018 | Huami | Zepp | Undisclosed | Multi-sports sensors (for Smartwatch technology) |
| Apr. 2018 | Myntra | Witworks | Undisclosed | Wearable tech (for shoes, watches and clothes) |
| Mar. 2018 | Fitbit | Solera | Undisclosed | Wearable tech (for healthcare) |
| Feb. 2018 | Fitbit | Twine Health | Undisclosed | Wearable-cloud software (for workplace wellness providers) |
| Nov. 2017 | Apple | Vrvana | 30 | AR and VR smart glasses technology |
| Nov. 2017 | Bose | Hush | Undisclosed | Hearable technology |
| Oct. 2017 | Microsoft | AltspaceVR | Undisclosed | VR smart glasses technology |
| Jan. 2017 | Fitbit | Vector Watch | 15 | (Software platform for) Smartwatch technology |
| Dec. 2016 | Google | Cronologics | Undisclosed | (Software platform for) Smartwatch technology |
| Dec. 2016 | Fitbit | Pebble Technologies | 23 | Smartwatch technology |
| Oct. 2016 | Google | Eyefluence | Undisclosed | AR and VR smart glasses technology |
| Apr. 2016 | Logitech | Jaybird | 50 | Hearable technology |

Source: GlobalData

The table below represents companies that have entered M&A with the digital health space over the past 2 years.

Table 12: M&A,Companies involved in Digital Health

| Announced Date | Acquirer | Target | Value ($M) | M&A Rationale |
|---|---|---|---|---|
| Jul. 2019 | Invitae Corp | Jungla | 40–50 | Enhance genetic testing offering |
| Jun. 2019 | Dassault Systems | Medidata Solutions | 5,800 | End to end R&D platform |
| Jun. 2019 | bioMerieux | Suzhou Hybiome Biomedical Engineering | 22.51 | Automated immunoassay test |
| May 2019 | Best Buy | Critical Signal Technologies | 7.96 | Electronic medical records |
| May 2019 | Apple Inc | Tueo Health Inc | Undisclosed | Asthma monitoring startup |
| Mar. 2019 | WELL Health Technologies Corp | Kela Atlantic Inc. dba KAI Innovations | Undisclosed | Wearable tech (for healthcare) |
| Feb. 2019 | Fitbit | Twine Health | Undisclosed | Wearable-cloud software (for workplace wellness providers) |
| Jan. 2019 | BioTelemetry Inc | Geneva Healthcare Limited | 65 | Expand remote monitoring for implantable cardiac devices offering |
| Jan. 2019 | Daan Dohmen | Omron Healthcare Inc | n/a | Accelerate international expansion for remote patient monitoring |
| Nov. 2018 | Medtronic | Nutrino | Undisclosed | Expand its diabetes offering with AI powered personalized nutrition platform |
| Sep. 2018 | OneLife Technologies Corp | Yinuo Technologies LTD - Mobile Health Monitoring Intellectual Property | n/a | Growing remote patient monitoring and telemedicine marketplace for a more complete mobile healthcare solution |
| Jun. 2018 | Omron Healthcare Europe BV | 3A Health Care S.r.l. | n/a | Expand respiratory offerings with the acquisition of the specialized aerosol therapy devices and surgical aspirators company |
| Apr. 2018 | SleepScore | Sleep.ai | Undisclosed | Expand its snore and bruxism-detecting wearables and apps |
| Apr. 2018 | Roche | Flatiron Health | 1,900 | Flatiron Health develops software that connects community oncologists, academics, hospitals, life science researchers, and regulators on a shared technology platform. |
| Mar. 2018 | DexCom | TypeZero Technologies | Undisclosed | Expand automation and accuracy CGM services for diabetic patients and HCPs |
| Jan. 2018 | Novartis Consumer Health | Quell Technology | 30.3 | Wearable pain relief brand |
| Dec. 2017 | Brain Sentinel | IctalCare A/S | n/a | Intellectual property and a non-prescription wearable Device |
| Aug. 2017 | Alphabet Inc | Senosis Health | n/a | Expand offering with the health apps which use smartphone's built in sensors to monitor different health biomarkers |

Source: GlobalData

## 5.11 Deals: Strategic Alliances

The key strategic alliances associated with the wearable tech theme over the last three years are listed in the table below.

Table 13: Strategic Alliances

| Announced Date | Companies Involved | Deal Headline |
|---|---|---|
| Jun. 2019 | Sanofi; Google | Sanofi and Google formed Innovation Lab as a joint venture |
| Mar 2019 | Eccrine Systems; Maxim Integrated Products | Eccrine Systems Enters into co-development Collaboration with Maxim Integrated Products |
| Mar 2019 | TPMENA; Nemaura Medical | TPMENA Enters into Licensing Agreement with Nemaura Medical |
| Feb. 2019 | Eisai; Empatica | Eisai and Empatica Enter into a Co-Promotion Agreement for Embrace2 Device |
| Nov 2018 | Insulet; Samsung Electronics America | Insulet Enters into Collaboration co-development Agreement with Samsung Electronics America |
| Sep. 2018 | Brainlab; Magic Leap | Brainlab and Magic Leap Enter into Co-Development Partnership |
| Sep. 2018 | Infosys; Google Cloud | Infosys Partners with Google Cloud under a co-development agreement |
| Sep. 2018 | Epicore Biosystems; LEO Science & Tech Hub | Epicore Biosystems and LEO Science & Tech Hub Enter into a co-development Agreement |
| Nov 2018 | Al-Danah Medical; Nemaura Medical | Al Danah Medical Enters into Distribution and Licensing Agreement with Nemaura Medical |
| Sep. 2018 | Nemaura Pharma; Global Pharma Company | Nemaura Pharma Enters into License Agreement with Global Pharma Company |
| May 2018 | Dallas Burston Ethitronix; Nemaura Medical | Dallas Burston Ethitronix Enters into Licensing Agreement with Nemaura Medical |
| Apr. 2018 | Chembio Diagnostic; LumiraDx | Chembio Diagnostic Enters into Co-Development Agreement with LumiraDx |
| Mar. 2018 | W. L. Gore & Associates; Bonbouton | W. L. Gore & Associates and Bonbouton Enter into Co-Development Agreement |
| Mar 2018 | DiA Imaging Analysis; Google Cloud Platform | DiA Imaging Analysis Enters into Co-Marketing Agreement with Google Cloud Platform |
| Jan 2018 | Gore; Kenzen | Gore Enters into a Co-Development Agreement with Kenzen |
| Jan. 2018 | Nuheara; National Acoustic Laboratories | Nuheara Enters into Licensing Agreement with National Acoustic Laboratories |
| Jan. 2018 | Sensoria Health; Optima Molliter | Sensoria Health and Optima Molliter Enter into a Co-Development Agreement |

Source: GlobalData © GlobalData

## 5.12 Timeline

This timeline represents some key developments in the history of wearable tech

Figure 12: Timeline


Source: GlobalData

## 5.13 Healthcare Case Studies

The case studies listed below demonstrate how wearable technology is being used in healthcare for improved outcomes.

### 5.13.1 Smarter Surgical Recoveries with Wearables (IBM)

Orthopedic advances have benefited many patients, from the first whole joint replacements such as the total hip replacements (THR) using the Teflon socket in the 1960s to the current surgical techniques, design of implants, and imaging modalities reducing surgical complications and improving outcomes. With the recent shift towards value-based healthcare, a more complete patient care pathway has evolved where better support and efficient care for beneficiaries undergoing orthopedic surgeries (such as knee and hip replacement) is essential. In a bid to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial surgery throughout the recovery, wearable technology offers great potential.

The Consensus TracPatch wearable technology offers a solution that tailors post-operative care to the individual patient while driving down cost through better patient outcomes for joint replacement surgeries. The TracPatch monitors the patient for the first six weeks of at-home recovery after total joint surgery. This enables visibility of the patient's activity at home during the most crucial recovery period, allowing care providers to access real-time data on a patient's postoperative progress.

The non-invasive wearable patch is fixed to a patient's collecting data such as range of motion, ambulation, exercise compliance, and wound site temperature. Data is transmitted continuously to a secure cloud-based platform, whereby physicians can track progress and intervene if necessary. The TracPatch is connected via Bluetooth to a mobile application allowing the patient to have an input in the control of their recovery.

The company is utilizing IBM Watson Health to capture, manage, and analyze data that help patients and healthcare professionals to improve outcomes. In addition to post-operative care, the TracPatch can be used strategically to monitor pre-operative patients tracking actual rather than reported mobility and activity.

The company has a reputation for total joint replacement (TJR) procedures which have fallen from high-priced $15,000 procedures to around $3,000. The falling prices of TJR, along with collaborations like TracPatch and Watson, facilitates a movement towards value-based healthcare, allowing hospitals with constrained budgets to utilize resources more strategically and see better patient outcomes.

GlobalData expects that as the smart wearable post-operative care market becomes a more competitive space, companies will have to either lower their pricing or exclusively target highly specialized indications.

Figure 13: TracPatch Device


Source: GlobalData



### 5.13.2 Moving towards "Virtual" Clinical Trials

As the pharmaceutical industry moves to integrate wearables into trials, earl results are promising for both sponsors and patients. For sponsors, they provide real-world data, lower costs, improve effectiveness via less clinical site time, earlier decision making, faster alerts to non-compliance, and improve success rates for trials moving from Phase II to III. Data aggregation provides the opportunity for observational studies, more insightful patient phenotyping, and increased post-market surveillance. For patients, wearables provide information into health, and reduce participation burden.

According to *ClinicalTrials.gov,* over 1,500 clinical trials have utilized wearables at some point during the trial process from as early as 2004. As of Q2 2019, over 540 of those trials are complete, with around 900 trials remaining active. Some of the common wearables utilized in the trials include ActiGraph, Fitbit, Garmin, Apple, and Empatica measuring biometrics and functionality such as activity tracking (accelerometry, step count, calorie burn), heart rate, heart rate variability, and sleep, as well as less-common biometrics including glucose monitoring, sweat analysis, electro-stimulation, UV tracking, and pressure sensors. Trials using wearables range from therapeutic areas from cardiovascular, neuroscience, respiratory, sleep, and stress to metabolic disorders, rheumatology, and pain, being used for clinical validation of wearable based endpoints. Wearable based endpoints widen the scope of research, with novel endpoints including mobility as a measure of quality of life, sleep studies at home across time, and more sensitive measures than traditional clinical scales in movement disorders such as using gait and tremor in Parkinson's disease.

Key considerations for sponsors with such a new technology include investment in infrastructure which may initially drive up costs, clearly defining endpoints, data (collection, flow, ownership, and processing and analytics), security, device characteristics (size, battery life), and any regulatory considerations. Additionally, trial sponsors need clear understanding of what type of data is expected from the wearable at the outset in order to correctly include in during research. For patients, concerns include privacy elements, data ownership, and patent education around data queries and the communication of how the data is being used. Current frameworks for wearables in clinical trials include the Clinical Trials Transformation

Initiative (CTTI) and Critical Path Institute (CPI) ePro Consortium. These provide recommendations for using wearables in clinical trials.

Learning from the data generated by wearables in clinical trials has often been stunted by poor quality data, lack of standardization and interoperability, and non-actionable insights generated by the data. Overcoming these issues is critical for clinical trials where research-ready platforms, are essential for high velocity, volume and standardized data collection and storage. Ongoing trials in the space include Litmus Health, whose platform is being used in conjunction with wearable devices in a 500 patient, 3-year study funded by Takeda Pharmaceuticals at David Rubin's Digestive Diseases Center at the University of Chicago. Initial results indicate that passive wearable monitoring can be used to predict elevated inflammatory markers in Inflammatory Bowel Disease (IBD), indicating endpoints such as flares and how they relate to patient activity and heart rate.

GlobalData expects that there will be increased collaboration between wearable technology device makers and sponsors running clinical trials, where companies will increasingly work with trial sponsors to either lower their pricing or exclusively target highly specialized indications/endpoints. Development of research-ready platforms will enable integration of wearables data into clinical trials, freeing up researchers and clinicians time from costly and time-consuming data engineering projects which have thwarted efforts to integrate novel endpoints.

With respect to endpoints, Key Opinion Leader's expressed the following:

*"If you're trying to decrease costs for cancer therapy after chemotherapy, you would then look at your cost of care, how many times the patients have to come back to the emergency room, how often they're readmitted after being discharged. If you're looking for flares in Crohn's, you would look for a decreased amount of patients having flares and then the associated costs with that. It really depends on what you're trying to measure but the things that get people most excited, obviously, are quality of life and cost."*

US Key Opinion Leader

*"Sponsors rarely know in advance what kind of data they want to get from the wearable. So the sponsor might know that they want to monitor sleep and they have some vague notion that the wearable will track sleep, but going from there to an actual metric for sleep is actually quite a bit of work."*

US Key Opinion Leader

Figure 14: ActiGraph Activity Monitor

Source: GlobalData



### 5.13.3 Advancements in Epilepsy Management with Wearable Technology (Empatica)

Empatica's Embrace device received FDA clearance for seizure monitoring in adults in January 2018, and received approval for use in children in 2019. The device represents the first epilepsy smartwatch to be cleared by the FDA, having been CE certified in Europe as a medical device for seizure detection in 2017.

The initial goal of the wearable wristwatch was to detect patterns in motion and physiological signals associated with tonic-clonic seizures, notifying caregivers in real time by transmitting changes in data via Bluetooth to a smartphone application. Seizure monitoring in epilepsy is important for patients, caregivers, and healthcare providers. With the added benefit that it is FDA certified for use in children, it significantly improves epilepsy management where patients, clinicians, and parents/caregivers can access data in real time, enabling better treatment and care.

Targeting tonic-clonic (or grand-mal) seizures is important for epilepsy sufferers, as the seizures have an association with sudden unexpected death in epilepsy (SUDEP). Medication adherence has been identified as one of the most important prevention strategies to control seizures, yet many people living with epilepsy struggle to control seizures using medication. Through identifying the onset of a seizure, caregivers can respond rapidly to provide care to the epilepsy sufferer during a seizure which is associated with better health outcomes.

Clinical testing using the Empatica Embrace device was carried out in an Epilepsy Monitoring Unit with 141 patients diagnosed with epilepsy including both pediatric and adult patients. The trial results indicated that the Embrace device detected tonic-clonic seizures with an accuracy rate of 98%.

The move towards better patient management for chronic conditions using smartwatches presents a huge opportunity. As chronic disease is on the rise, the potential to better manage the treatment pathway and care outcome is huge. More targeted devices specific to a therapeutic indication are likely to emerge over the next 5–10 years.

Figure 15: Empatica Embrace Smartwatch

Source: GlobalData



### 5.13.4 Advancements in Diabetes Management with Wearable Technology

Diabetes mellitus is on the rise across the globe. Once an illness affecting more developed countries, its prevalence is on the rise in less developed countries in combination with obesity and sedentary lifestyles, which is driving med tech companies to develop wearable devices to manage the condition. Managing diabetes requires a multi-disciplinary approach to help control blood glucose while adjusting lifestyle conditions such as activity levels and the correct diet. Devices that autonomously monitor blood glucose levels have a great opportunity.

Traditional players in the space include Google and Apple with wearables including wristbands, smartwatches, skin patches, smart shoes and socks, and contact lenses. However, the most common wearable device for diabetes management is a continuous glucose monitoring (CGM) device which continuously monitors blood glucose 24/7, such as the K'Watch CGM device.

PKvitality markets its K'Watch as a minimally invasive smartwatch to measure glucose on a continuous basis utilizing K'apsul and SkinTaste technology. Compared to other marketed devices, which include a smartwatch with an implantable sensor, this provides one of the first instances of a completely non-invasive CGM. The watch both measures glucose level and displays it continuously to assess any trends over time and create customized automated alerts to prevent hyper- or hypoglycemia episodes. There is an additional option for the user to share their data with healthcare professionals or caregivers.

GlobalData predicts that the development of wearable technologies targeting diabetes will increase significantly over the next 5-10 years in response to increasing prevalence of the disease, where in the US it is growing at a CAGR of 0.28%. Many existing GCM sensors are aimed towards Type 1 diabetes, which represents only 5-10% of total diabetes. There is a huge market potential still available for development of CGMs for type 2 diabetics, as well as targeting the pre-diabetic market and potential non-diabetics taking part in wellness or fitness programs. GlobalData estimates that it will grow considerably between 2019-2025 where the global rise in diabetes and advancements in wearable technology facilitating CGM delivering precise and reliable real-time monitoring will drive the market forwards.

Figure 16: PKvitality Watch (Left) and K'apsul, Using SkinTaste Technology (Right)


Source: GlobalData



### 5.13.5 The "Gold Standard" – Scandinavia

Scandinavian and Nordic healthcare is based on a strong history of a common approach to social welfare that is taxation based and locally administered, with every citizen having equal access. According to a study published by the Lancet, Scandinavian and Nordic countries had the highest level of quality and access when compared with 195 countries across 25 years, including Western and OECD nations. One contributing factor in Sweden's system is its efficient documentation of patient health outcomes, with data forming "national quality registries." The patient-individualized data allow HCPs to assess outcomes-based data with a long-term view, accessible by any HCP or healthcare institution.

*"You only need to look at Scandinavia to see how it's done. You get a unique identifier which you verify with your bank ID. It's a record that is shared between every pharmacy, every hospital, every ambulance driver, GP, consultant, hospital. Prescription comes from wherever and looks at your bank ID, and able to access it as a unique identified prescription for you to collect whenever you like. It's obvious."*

EU Key Opinion Leader

*"Only in a few countries, like in Denmark and maybe Estonia, there are incentives for physicians to be pushed or motivated to use digital health technologies and learn about them. And also, they encourage their patients to use them because they are partners they can ask for help in this jungle of health information."*

EU Key Opinion Leader

### 5.13.6 Remote Patient Monitoring and Vulnerable Patient Populations: Proteus and DTx

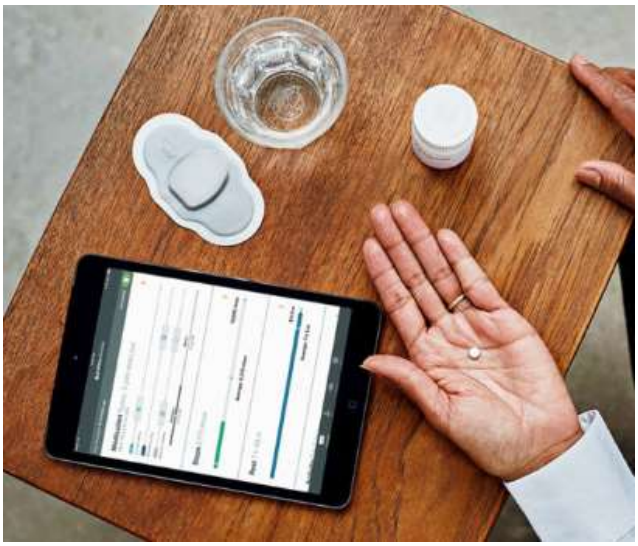
Proteus Digital Health and Otsuka Pharmaceutical launched the Abilify MyCite system to record drug ingestion embedded with an Ingestible Event Marker (IEM) sensor, used alongside a wearable sensor patch, an application on a mobile device and a provider portal. After receiving FDA approval in Q4 2017, doctors are able to monitor the intake of Abilify MyCite by

remotely ensuring adherence and correct drug dose and timing for their patients with schizophrenia, bipolar disorder, and depressive disorder. For a disease area that is notoriously difficult to treat with low adherence to medication within a vulnerable patient population, the product has huge efficacy, while payment structures for the therapy are outcome-based.

This represents an increasingly important area of medicine as remote patient monitoring refers to the measurement and analysis of a patient's health metrics, as well as diagnosis and/or treatment, which would traditionally require a patient be physically present within a clinical setting or with a healthcare professional. Wearables and RPM devices gather time-sensitive information, improving diagnostic capabilities and intervention where necessary, ultimately improving patient adherence to medication and overall outcomes. Through providing patients and caregivers the option to provide care at home, this reduces unnecessary visits to healthcare establishments moving towards a more decentralized model, optimizing the allocation of resources in hospitals and clinics. This has implications across the entire healthcare value chain, changing the delivery and supply of healthcare, while traditional tech companies become embedded within the ecosystem with calls to change reimbursement strategies.

This is changing how pharma and healthcare operates on the whole, with increasing collaboration across tech as the ecosystem begins to understand the impact that RPM can have on improving efficiency and control, reducing cost of production, augmenting use of resources and minimizing wastage, owing to better visibility and control. In healthcare settings, this will reduce pressure on doctors, medical professionals, hospitals, and pharmacies, and insurers in certain markets, with better understanding of the insured health. In the future, doctors' roles may evolve to treat more advanced care, with automated prescription services with the ability to modify prescription drugs in real-time, accelerating the drug supply chain.

Figure 17: Proteus System with Ingestible Sensor, Patch and Mobile Application



Source: GlobalData

## 5.1 Final Remarks

*"There is the financial incentive. If we can look to previous stakeholders, patients, and clinicians, the better we manage the system, and so the better the patients are managed, clinicians' time better used, then healthcare in a time of more demand and restricted resources will have the tools to make better strategic planning of healthcare resources. So I think I see tremendous, positive effect."*

US Key Opinion Leader

*"To say that this [wearable technology] is going to be so easy and so common that we're almost going to be surprised that we didn't do it before. We're not going to imagine an era where we didn't measure your heart rate continuously… even EKG continuously with a wearable device that also gives us the time or connects us with physicians or with grandma. It's all going to be pretty much part of our culture, our common life."*

US Key Opinion Leader

*"I think, in the next couple of years, it's going to be this blanket of Internet of Things, connected devices, and we just have to figure out how to balance the privacy and security with the benefit."*

US Key Opinion Leader

*"The future I envision is one very much of bring-your-own-device. And so, I think that the future I would like to see is where a patient is at their physician's and the patient has a wearable, or is using their phone as a tracking device, and that that device conforms to some sort of standard which allows it to be integrated seamlessly into their own healthcare paradigm. So, you know, whether it's Fitbit, or Garmin, or some other type of wearable, or an iPhone, or an Android, there is some published standard that the industry has agreed upon, that, once you conform to that standard, then, you know, the electronic health record vendors or whoever will be able to integrate those data into the patient's own care."*

US Key Opinion Leader

*"Anything that helps monitoring the patient in a non-invasive manner, it will have an enormous role to play in managing disease."*

EU Key Opinion Leader

*"One of my main concerns is how well designed is the application side of the sensor. Not the sensor itself, but how the sensor captures, processes, and communicates their advice to the user. That is tremendous because it's very easy for individuals to generate fatigue from using a device. So, I'm not feeling motivated, I'm finding that fatigue is one of the detriments of using the device. And that is not about passing superfluous, shallow messages to the patient, but actually, it's about thinking deeply about the disease and what actually can make a difference to the patient. It's thinking about that design very deeply. Because what happens in the market is that...or what I see is that people in companies, they just want to produce something. They*

*produce something, the device tells you every day that you have done 5,000 steps. Whereas if you had, as a part of that surveillance, a system that provides you with actions rather than just assessments, that only would be of tremendous use."*

EU Key Opinion Leader

*"I think the activity is going to be the first one… but I think we're going to move quickly into other areas of real-world data or the 'Sociome' as we talk about, you know, things like diet, travel, environmental factors. I think those are all going to be eventually incorporated."*

US Key Opinion Leader

# 6 Companies Section

In this section, GlobalData highlights the listed companies and private companies that are making their mark within the Wearable Tech theme.

## 6.1 Tech Companies

In this section, GlobalData highlights companies that are making their mark within the wearable tech theme.

Table 14: Tech Companies

| Company | Country | Competitive position in the wearable tech theme |
|---|---|---|
| Apple | US | Apple leads the market after entering in 2015 with its first smartwatch, rapidly expanding into hearables with the Apple AirPods in 2016, and starting AR smart glasses development in 2018 with the acquisition of Akonia Holographics. Apple is steadily adopting newer technologies to drive standalone operability of its devices, such as LTE capability on Apple Watches and Siri on Apple AirPods. Apple is enhancing the role of these technologies as healthcare-oriented devices in the expanding IoT ecosystem. |
| Facebook | US | With steady improvement in VR technologies and Oculus's low-cost models gaining commercial prominence in Western countries, Facebook plans to sell a billion Oculus VR headsets globally. While growing AR tech and the slow adoption rate of VR in most countries—attributed high price and limited use cases—remain key challenges for the company in achieving its desired results, Facebook's Oculus devices are successfully outpacing the nearest competitors, Sony PS VR and HTC VR devices. Facebook in-house engineers are also working on a wearable band that can teach people how to feel words. Inspired from Braille and Tadoma, the band enables the wearer to "read" incoming smartphone messages in the form of vibrations. |
| Fitbit | US | Fitbit is a pioneer in the wearable technologies domain and offers a range of connected health and fitness devices that include fitness & smartwatches, wristbands, activity trackers, and wireless headphones. The company offers a personalized online dashboard and mobile apps that sync automatically with and display real-time data from wearable devices. The Fitbit platform also offers social features, such as access to an online community of users, leader boards, and challenges, which allow users to receive and provide support and engage in friendly competitions. The company's NFC-based payments service platform, Fitbit Pay, enables users to pay via credit or debit card through supported Fitbit smartwatches. FitBit recently announced their push into the smartwatch market, after seeing a 70% revenue growth in its Health Solutions program, which primarily caters to employers and payers. |
| Garmin | US | Garmin offers a range of products designed for use in fitness and activity tracking. The company's fitness trackers and ruggedized GPS smartwatches are marketed worldwide; however, its major clientele are located across North America, Europe, and the Middle East & Africa. Following the strategies of its peers, Garmin introduced the wearables payment platform Garmin Pay, and LTE enabled smartwatches. The company also offers Garmin Connect and Garmin Connect Mobile platforms for users to track, analyze, and share their fitness and wellness data, and compete with community members. |
| Google (Alphabet) | US | Despite being a frontrunner in developing wearable technologies, Google encountered challenges in the appropriate positioning of their devices in the commercial market. The Google Glass failed to gather traction in the market, while the Wear OS is often complained about by smartwatch makers to be an underperformer when compared to Apple's watchOS. However, the Wear OS remains the most preferred choice for numerous smartwatch OEMs. It is anticipated to undergo an overhaul when Google initiates development of the long-awaited Pixel Watch. Meanwhile, Google re-introduced the Google Glasses Enterprise Edition in 2017, specifically targeting industrial applications. |
| HTC | Taiwan | The Taiwanese consumer electronics company stands as a leader in the VR sector. The company sold off its mobile manufacturing segment to Google, with plans to invest more aggressively in maturing their VR competencies. In partnership with Valve Corporation, HTC designed VR devices for Steam users. The Vive series VR headsets are directly competing with Facebook's Oculus headsets in the global market. |
| Huawei | China | Huawei offers low-cost fitness trackers and smartwatches in the global wearables market. Within a period of 3–4 years since its foray in the wearables market, Huawei has excelled in blending wearable technologies with the in-demand fashion attributes. The backward integration initiatives to develop its own smartwatch chips and OS promote reduced dependency on other vendors and drive more self-containment. The latest Huawei Watch GT includes its custom silicon chips and features the Lite OS as a replacement of the Wear OS. Expanding its portfolio, Huawei's initial collection of basic smart glasses—developed in collaboration with Korean brand Gentle Monster—is expected in the second half of 2019, while AR-based smart glasses are set to be launched in 2020—2021. |
| Microsoft | US | Despite being an early entrant in the wearables market with the Microsoft Band, Microsoft's present involvement in the sector is largely confined to the smart glasses segment. While its competitors emphasized VR and AR, Microsoft went a step ahead to develop the Mixed Reality (MR)-based HoloLens and HoloLens 2.0 – which the company is presently positioning more as an enterprise solution than consumer product. Absence of significant competition in the MR segment provides |

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| | | Microsoft with a strong position to benefit from the HoloLens devices. The company also holds patents for new fitness-focused smart rings and bands. |
| Qualcomm | US | Qualcomm has been a steady endorser of wearable technologies and is involved in developing custom silicon chips for wearable devices, primarily for OEMs utilizing the Google Wear OS. In September 2018, Qualcomm introduced its latest smartwatch chipset called the Snapdragon Wear 3100. To establish this new chipset as a catalyst in development of next-gen wearable devices and expand the prominence of the Qualcomm Snapdragon Wear family of wearable platforms, it collaborated with original design manufacturers such as Compal Electronics and Longcheer on smartwatches, Huaqin and Thundersoft on 4G kids' watches, Franklin Wireless on 4G smart trackers, and Smartcom on 4G connected end-to-end solutions. Qualcomm's Wear 2500 is specifically designed to serve on kids' watches. |
| Samsung | South Korea | Samsung's wearable portfolio includes smartwatches, smart fitness trackers, and VR headsets. Although its initial wearable devices were developed in association with other firms—Samsung Gear VR with Oculus VR and Samsung Gear with Google—the company gradually took control over the subsequent developments. Samsung eventually replaced the Android Wear OS with its own Linux-based Tizen OS and initiated developing its Exynos SoC microprocessors for its smartwatches. In terms of VR devices, the company presently develops both software and hardware all by itself. Samsung has also expanded into the hearables segment with the Samsung Gear IconX, which is presently in the second generation. Realizing the growing potential of wearables, Samsung is aggressively positioning its smartwatches in enterprise applications. It is also taking strides in smart clothes – a very less crowded segment that is gradually gaining market traction. The company stands as a leading wearables vendor in Asia Pacific, Europe, and the Middle East and Africa. |
| Sony | Japan | Sony's wearable offerings include smartwatches, activity trackers, and VR headsets. However, Sony's technology integration has been significantly slower than other players in the market. The company's PlayStation (PS) VR is primarily targeted to the gaming populace and works with the PS4 console. No backward integration or upgraded VR model have been announced while the PS4 console is already in the last years of its life. Similarly, its SmartBand activity tracker series falls short of the latest healthcare-focused functionalities. However, Sony integrated calling capabilities in the activity tracker and relaunched it as SmartBand Talk. In 2019, Sony introduced the Sony Wena straps, which, when connected to a traditional watch, enables watch-based contactless payment, basic fitness tracking, and notification access from the connected phone. |
| Vuzix | US | Vuzix is an emerging brand in the wearables market which offers display technologies and software products. In 2015, Intel acquired a 30% share of the company for $24.8M and in 2017 Blackberry partnered with it to develop enterprise-specific smart glasses. Vuzix's personal display devices find applications in gaming, manufacturing, training, and military tactical equipment. The company has also been a consistent promoter of smart glasses applications in enterprises, supported DHL's "Vision Picking" program, and developed a customized Windows-based USB-C Type C AR smart glasses for Toshiba. The company is presently involved in development of a waveguide-based HMD for use in US military aircraft. |
| Xiaomi | China | Xiaomi, often referred to as "the Apple of China", is the leading wearables vendor in China and holds strong command in multiple matured markets, including the US. The company procures wearable devices, especially smartwatches, from its exclusive technology partner, Huami. Its offerings also include the Mi Band fitness trackers, which accounted for nearly one quarter of the company's shipments in Q4 2018. The company is known for delivering high-tech devices at low prices. In the domestic Chinese market, Xiaomi's rapid growth also challenges the dominance of Huawei. Xiaomi is set to introduce new wearables in 2019, which are likely to feature Huami's new Huangshan -1 chip that is capable of screening heart rate patterns of users via cloud-based AI. |

Source:GlobalData

## 6.2 Wearable Technology Companies – Healthcare

The table below lists healthcare companies with a strong competitive position in the wearable technology space.

Table 15: Healthcare Wearable Companies

| Company | Country | Competitive Position in the Wearables Theme | Public/Private |
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| AliveCor | US | AliveCor is a medical device and AI company that develops and manufactures ECG hardware and software for mobile devices. The company provides Kardia, an AI-enabled platform to help clinicians manage patients for the detection of atrial fibrillation and normal sinus rhythm in an ECG. It offers KardiaMobile and KardiaBand applications. AliveCor provides portable device, early detection, immediate feedback, and convenient short-term and long-term self-monitoring solutions. The company offers key clinical validation studies that include arrhythmia assessment, early detection, post-ablation, and post-surgery. | Private |
| Ambiotex | Germany | Ambiotex is a German company specializing in medical device-enabled clothing. They specialize in shirts with embedded sensors that measure multiple healthcare parameters including heart rate, pulse, calorie consumption, and more. | Private |
| Amiigo (Wavelet Health) | US | Wavelet Health is a privately-owned medical device company based in the US. They specialize in wearable devices and mobile applications that maximize cloud computing and machine learning capabilities. Their devices measure multiple physiological parameters. | Private |
| Athos | US | Athos is a US-based company that develops smart clothing specifically marketed towards athletes. | Private |
| BioBeat | Israel | BioBeat Technologies an Israeli-based technology company specializing in wearable blood pressure monitors. The BioBeat patented platform uses a reflective measurement approach, where a photoplethysmograph (PPG) signal is received free of background noise via either a wristwatch or a patch. | Private |
| Biolinq | US | Biolinq is a privately-owned medical device company based in the US. They have developed a proprietary sensor system and incorporated it into their wearable continuous glucose monitors. | Private |
| BioTelemetry | US | BioTelemetry is a wireless medical technology company, focused on providing monitoring services and digital population health management in a healthcare setting, medical device manufacturing and centralized core laboratory services for clinical research. The company offers various services and solutions to cardiologists and electrophysiologists, which provides them with a single source of cardiac monitoring services such as mobile cardiac telemetry service (MCT), wireless and trans telephonic event, traditional Holter, extended-wear Holter, pacemaker, and International Normalized Ratio (INR) monitoring. The company is also engaged in developing, manufacturing, testing, and marketing medical devices. The company has operations in the US and the UK. | Public |
| Bonbouton (diabetes) | US | Bonbouton is a US-based medical device company. Their first product is a smart insole that detects foot ulcers in diabetic patients before they form. Their technology incorporates graphene sensors that can measure physiological parameters. | Private |
| Bose | US | Bose is a manufacturer and marketer of audio products. The company designs, manufactures, and markets audio equipment such as stereo speakers, computer speakers, outdoor and marine speakers, amplifiers, headphones and headsets, wave systems, home theater systems, SoundDock systems for iPod, automotive sound systems for luxury cars, and automotive suspension systems. The company markets its products under Bose, CineMate Lifestyle, Wave, SoundTouch, SoundDock, PackLite, QuietComfort, SoundSport, and SoundLink brands. The company provides its products to various arts centers, theaters, houses of worship, stadiums, arenas, restaurants, retail stores, corporate buildings, and hospitality establishments. The company operates across North America, South America, Europe, Australia, and Asia-Pacific. | Private |
| Brain Sentinel | US | Brain Sentinel is a US-based private company and developer of wearable seizure-sensing devices. Their SPEAC System monitors for seizures and provides alerts and information. | Private |
| Byteflies | Belgium, US | Byteflies is a Belgian-American company that provides business-to-business services for companies developing wearable technology devices. | Private |
| Cardiomo | US | Cardiomo is a US-based private company that develops wearable sensors for heart health. Their device is non-invasive and wearable. | Private |
| Cosinuss One | Germany | Cosinuss is a Germany-based company with a specialization in in-ear wearable medical devices. Their first product, the Cosinuss One, is targeted at professional athletes as a way to measure key physiological vitals. They are currently developing a second device, a smart fever assistant. | Private |
| Eccrine Systems | US | Eccrine Systems Inc is a provider of a wearable device that measures drug and biomarker levels | Private |

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| | | excreted in sweat. | |
| Empatica | US | Empatica is a medical device company. The company is focused on the development of sensory devices based on electrodermal activity for identification of convulsive seizures. The products offered by the company include the Embrace smartband, seizure alert app, Mate seizure diary app, and E4 wristband. Its clients include Danny Did Foundation, Epilepsy Foundation, Boston Children's Hospital, NASA, and Sunovion. | Private |
| Epicore Biosystems | US | Epicore Biosystems is a provider of a single-use sweat analytics system for athletes. Its technology includes a sweat microfluidic sensing platform that is “skin-like,” low-cost, and capable of analyzing small droplets of sweat directly from the skin. Epicore has been working with Gatorade to commercialize its technology, and is in the process of launching the microfluidic Gx Sweat Patch. | Private |
| Epson | US | Epson focuses on developing technologies in the areas of visual communications, robotics, sensing, and business and commercial digital imaging. Its focuses is across sports, fashion, augmented reality, and personal healthcare. The company has operations in the Americas, Europe, Asia, Oceania, the Middle East, and Africa. | Private |
| eSight | Canada | eSight Corp is a provider of eSight, a wearable electronic glass for visual impairment people. The glass helps legally blind to virtually see the things and manage their daily activities. | Private |
| Everist Health | US | Everist Health is the developer of the Angiodefender. This non-invasive medical device uses sensors to detect cardiovascular disease in its early stages. | Private |
| Floreo | US | Floreo is a start-up company based in the US that is developing virtual reality devices to deliver learning to children with autism. | Private |
| Gentag | US | Gentag is a medical device company that patents and develops wireless sensor technology products. The company provides wireless products to diagnostics and personal health. It offers wireless sensor network services. Gentag’s products comprise medication and packaging sensors, diagnostic skin patches, immunoassays, cell phone home monitoring solutions systems, cell phone sensors, NFC cell phones, and radar responsive tags, among others. The company offers solutions for hospital discharge kits, radiation, phone immunoassays, chemical and biological detection, and cell phone applications, among others. Its RFID technology is used in the areas of radar responsive tag, asthma prevention, diagnostics, and diabetes, among others. | Private |
| GOQii | US | GOQii is a US-based company with offices in Shenzhen and Mumbai. It develops wearables such as a fitness tracker band as well as cloud ecosystems for medical information. | Private |
| GreenTEG | Switzerland | GreenTEG is a company that specializes in high-precision thermal sensors. | Public |
| Gaugewear | US | Gaugewear is a US-based company that has developed non-invasive wearable devices for measuring the body's core temperature. | Private |
| Halo Neuroscience | US | Halo Neuroscience is neurotechnology company that develops solutions for enhancing brain performance. Its Halo Sport is a headset exclusively designed for athletes that help to improve their brain’s response to training and drive accelerated performance gains. Halo Sport uses proprietary technology called Neuropriming, which is the process of using electrical stimulation during movement-based training to build stronger and optimized connections between user’s brain and muscles. | Private |
| Hexoskin | Canada | Hexoskin is a Canadian company specialized in development of smart clothing that measures body metrics. It also provides technology platforms and data analysis services. | Private |
| Immersive Solutions | Australia | Immersive Solutions is a provider of digital learning. It specializes in incorporating VR into its systems for a more immersive solution. | Private |
| Infineon | Germany | Infineon Technologies AG (Infineon) is a provider of semiconductor solutions. Through its subsidiaries, the company designs, develops, manufactures, and markets application-specific ICs, automotive system ICs, diodes, evaluation boards, electrostatic discharge protection, and electromagnetic interference protection products. It also offers micro controllers, radio frequency and wireless controls, security ICs, smart card ICs, sensors, interfaces, and transistor products. Infineon provides mobile phones, analog and digital TV tuners, satellite radio receivers, and radio frequency power transistors. The company caters to automotive, security, consumers; commercial, construction, and agricultural vehicles; data processing, electro mobility, industrial, lighting, medical, mobile devices, motor control and drives; motorcycles, e-bikes, and e-vehicles; power supplies, smart grid, solar energy systems, and wind energy system applications. | Public |
| iRhythm | US | iRhythm Technologies is a digital healthcare solutions company. It provides non-invasive long-term cardiac rhythm monitors. The company develops the Zio family of products and solutions to address the clinical needs of patients suffering from arrhythmias. iRhythm’s product offerings include Zio XT and Zio AT Patch, a long-term cardiac rhythm monitors. Zio XT service is a long-term | Public |

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| | | continuous cardiac monitor that detects arrhythmias including AFib. The company offers ZIO Service in the US to physicians, hospitals, and clinics through a direct sales organization. | |
| IrisVision | US | IrisVision is a private, US-based company that has developed a wearable headset that helps the visually-impaired see better. | Private |
| Jabra (GN Group) | Australia | GN Group develops audio solutions for people with hearing loss, with their sports segment developing hearables for athletes with its Jabra Elite Sport range including real-time coaching, heart rate sensing, and VO2 Max testing, plus sweat and waterproofing. | Public |
| Jawbone Health (in development) | US | Jawbone was an American privately held consumer technology and wearable products company headquartered in San Francisco, California. Since June 19, 2017, it has been undergoing liquidation via an assignment for the benefit of creditors. It developed and sold wearable technology such as wristbands and portable audio devices, wireless speakers, Bluetooth headsets, and related technology. Jawbone marketed its wearable products as part of the IoT. In May 2019, Jawbone Health was launched with $65M for wearable driven health-monitoring devices to identify and prevent health conditions. Jawbone Health's transition into health services is in parallel with its long-term competitor, FitBit, which recently announced its push into the smartwatch market after seeing a 70% revenue growth in its Health Solutions program, which primarily caters to employers and payers. | Private |
| Karuna Labs | US | Karuna Labs is a privately owned company that develops VR-based medical devices to help people suffering from neuropathic pain. Their devices incorporate graded motor imagery, biofeedback, and pain psychology protocols. | Private |
| Kenzen | US | Kenzen is a US-based company. It has developed a biometric patch that detects heat, fatigue, and overexertion. Its product is targeted towards industrial employees. | Private |
| KinesiaU | US | KinesiaU has developed wearable devices for people with Parkinson's disease. Their portfolio includes the Kinesia One, the Kinesia 360, and the Kinesia U. | Private |
| Komodo Tech | US | Komodo Tech is a US-based company that has developed the AIO Sleeve, a medical device that accurately measures heart rate variability. | Private |
| Lifesense Group | Netherlands | Lifesense Group is a developer of wearable medical technology designed for people with stress urinary incontinence. Their products include the Carin (for women) and the Wil (for men). | Private |
| LumiraDx | UK | LumiraDx specializes in connected healthcare solutions for diagnostics and IT businesses. | Private |
| Lumo | US | Lumo Bodytech has developed a technology platform that leverages smart sensors and software to optimize performance and address human biomechanics through the real-time tracking of body movement. Current Lumo Bodytech products include the Lumo Lift and Lumo Back posture coaches and activity trackers, as well as the Lumo Run smart running sensor. | Private |
| Magic Leap | US | Magic Leap is a light-field-display technologies developer for virtual animations and virtual reality experiences. The company offers the Magic Leap One Creator Edition headset. It is a next generation computing platform, which enables users to experience both physical and digital worlds. Magic Leap One also enables web developers to develop spatial browsing and content extraction and create and play games. Magic leap collaborates with research centers, technology providers, and film and television production houses. | Private |
| Medtronic | Ireland | Medtronic Plc (Medtronic), formerly Medtronic Inc, is a medical technology company that designs, develops, manufactures, and markets a wide range of medical devices and solutions for the treatment of heart failure; heart valve disorders; coronary artery, aorta, peripheral vascular, venous renal, and neurological diseases; spine and musculoskeletal disorders; and diseases of the ear, nose, and throat. It also provides biologic solutions for the orthopedic and dental markets. In the US, the company sells its products through direct sales force, and in other countries through direct sales representatives and independent distributors. It serves hospitals, third-party healthcare providers, clinics, institutions including governmental health care programs, distributors, and group purchasing organizations in Asia Pacific, Europe, the Americas, the Middle East and Africa. | Public |
| Milo | US | Milo Sensors produces a transdermal sensor that measures alcohol consumption. | Private |
| MindMaze | Switzerland | MindMaze SA (MindMaze) is a neurotechnology company that develops VR-based products that help patients with brain trauma and amputations to stimulate neural recovery. Its computing platform captures brain activity upon intent, creating a new operating system for computers – a mindOS, while its intuitive mind/machine interface utilizes real-time decoding of brain signals via neural prediction. Its innovations are poised to transform industries such as healthcare and gaming. The company's product offerings include MASK and MindMotion Pro. | Private |
| MisFit | US | Misfit is a manufacturer and retailer of wearable and smart home products based in the US. The company provides smart watches, fitness trackers, and accessories. Its fitness trackers monitor the | Private |

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| | | behavior and lifestyle of users and deliver insights, helping to stay fit and healthy. | |
| MyManu | UK | MyManu is a UK-based company that develops smart sound systems, including earbuds. | Private |
| Nemaura Medical | UK | Nemaura Medical is a UK-based company. It develops smart patches for continuous monitoring of multiple health conditions, including diabetes. | Private |
| Neofect | South Korea | Neofect is a manufacturer of smart medical devices for the purposes of rehabilitation. Their product portfolio includes multiple smart gloves and smart boards. | Private |
| Nike | US | Nike is a manufacturer of sporting goods, including wearables that track physiological parameters such as heart rate. | Public |
| Nuheara | Australia | Nuheara is a developer of smart hearing solutions for the hearing-impaired. | Public |
| NeuroMetrix | US | NeuroMetrix Inc (NeuroMetrix) is a healthcare company that develops wearable medical technology and point-of-care testing to manage chronic pain, nerve diseases, and sleep disorders. The company's products include Quell wearable pain relief device, Quell health cloud, DPNCheck point-of-care neuropathy test, and the Advance system. Its DPNCheck is used for the treatment of diabetic peripheral neuropathy. NeuroMetrix offers services in basic and clinical neurophysiology, biomedical engineering and instrumentation, and information technology. The company serves clinics, hospitals, managed care organizations, retail health businesses, and durable medical equipment suppliers. It markets its products through its network of distributors in Americas, Europe, Asia, and the Middle East. | Public |
| Omron | Japan | Omron manufactures and markets automation components. The company supports manufacturing innovation through advanced automation technologies and products and extensive customer support. It also offers social systems and healthcare equipment. The company provides built-in control components for automotive devices, commercial and customer devices, industrial equipment, environmental and energy devices, and built-in components for mobile devices. Its offerings include electricity storage systems, solar power conditioners, electrical power measuring devices, uninterruptible power supplies, power protection devices, OEM development, and manufacturing of electronic equipment among others. It manages its worldwide operations through its regional management centers in Japan, North America, Europe, Asia-Pacific, and China. | Public |
| OneLife Technologies | US | OneLife Technologies is a mobile medical software/data collection company with a suite of proprietary, patented, medical-grade tracking technologies designed to provide patients, physicians, nursing homes, and hospitals with real-time centralized, personal, comprehensive health data and monitoring. The system and devices will be HIPAA-compliant and utilize an open API for easy data communication and integration to any existing EMR system. | Private |
| Owlet | US | Owlet Baby Care (Owlet) offers a Smart Sock that tracks heart rate and oxygen levels of infants while they sleep. The devices provide better insights into the health and well-being of infants and notify users in real-time in case of any unusual measurements. | Private |
| PAI Health | Canada | PAI Health is a Canadian company that develops wearables allowing the user to track their exercise. Their wearables incorporate weekly activity goals with personalized information on exercise needs. | Private |
| PKvitality | France | PKvitality is the manufacturer of a smartwatch that contains continuous glucose monitoring capability. | Private |
| Qardio | US | Qardio offers tech products with data analytics for connected health devices. Its Qardio products are clinically-validated including QardioArm, QardioBase, QardioCore and QardioMD. | Private |
| Roche | Switzerland | F. Hoffmann-La Roche (Roche) is a biotechnology company that develops drugs and diagnostics to treat major diseases. It provides pharmaceuticals in the cancer, neuroscience, infection, immunology, ophthalmology, cardiovascular and metabolism, hematology, neurology, and respiratory disease areas. The company also provides in vitro diagnostics and tissue-based cancer diagnostics, besides diabetes management solutions. Roche conducts research to identify novel methods to prevent, diagnose and treat diseases. The company offers its products and services to hospitals, commercial diagnostic laboratories, healthcare professionals, researchers and pharmacists. Together with its subsidiaries and partners, the company has operations in various countries all over the world. | Public |
| Sennheiser | Germany | Sennheiser is a producer of audio products including headphones, microphones, and wireless transmission technology. | Private |
| Senseonics | US | Senseonics, a subsidiary of Senseonics Holdings Inc, is a medical device company that designs, develops and commercializes glucose monitoring products. Its products include Eversense and Eversense XL, implantable CGM systems that help people with diabetes to continuously measure their glucose levels from the interstitial fluid below their skin surface using a sensor, transmitter, and mobile medical application. The company distributes products through a network of third- | Private |

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| | | party distributors in Europe and through distribution agreements with various medical device companies in rest of Europe, the Middle East and Africa, Asia Pacific, and Latin America. | |
| Sensoria | US | Sensoria (formerly Heapsylon) is focused on delivering a family of body-sensing devices for the human foot. The company's wearable products capture and communicate data such as activity type, body weight, eversion and in-footwear pressure to the user. The data is presented and analyzed in a mobile dashboard. Its products contribute towards preventing certain injuries during exercise. It also tracks patient adherence and offloading data in case of injury or disease. | Private |
| Siren | US | Siren Care is a medical technology company that developed diabetic socks that organize and track foot temperature of diabetic foot ulcers patients through an application. Siren's smart diabetic socks and foot monitoring system is built with neurofabric, a smart textile built with seamless embedded miniature temperature sensors for ulcer detection and amputation prevention to avoid complications caused by chronic disease and aging. | Private |
| SmartMonitor | US | SmartMonitor is a US-based company that develops monitoring technology. Its Inspyre product can detect movements and is compatible with the Apple Watch. | Private |
| Spire Health | US | Spire Health is a US-based company that specializes in remote monitoring for respiration across a number of disease and disorder indications, including chronic obstructive pulmonary disease (COPD), congestive heart failure, asthma, sleep disorders, and anxiety. | Private |
| Theranica | Israel | Theranica is an Israeli company that specializes in non-invasive, wearable neuromodulation devices for the treatment of migraines. | Private |
| Under Armour | US | Under Armour is a sporting goods company that specializes in athletic clothing. They also develop smart clothing for biometric tracking and have invested in multiple health and fitness mobile apps. | Public |
| Viatom | China | Shenzhen Viatom Technology Co. (Viatom) develops, manufactures, and distributes medical devices. Its medical suite of products includes Checkme Pro, Checkme Lite, Checkme O2, HeartMate ECG Monitor, AirBP, and FPO-10 Pulse Oximeter. Its Checkme Pro performs as ECG recorder, pulse oximeter, mini monitor, pedometer, BP tracker, thermometer, sleep monitor, and daily spot check device. Its Checkme Lite is a device that facilitates daily checkup, ECG recording, pulse checkup, and blood pressure tracking. Viatom's Checkme O2 is a medical watch for snorers that facilitates HR and motion monitoring, detects oxygen drops that are caused by sleep apnea, and vibrates to help overcome oxygen shortage. | Private |
| VivaLNK | US | VivaLnk is a Telehealth company that offers eSkin, a breathable electronic substrate for delivering biometric data. The device enables continuous health monitoring of users and wirelessly sends the information to their mobile devices including tablets and smartphones. The company also offers array of health monitoring products such as Fever Scout, VivaBear, and Vital Scout. | Private |
| Vivomi | US | Vivomi develops a wearable heart rate monitor that assesses heart rate variability. | Private |
| Wearable X | US | Wearable X is a fashion technology company that incorporates biosensors with vibration feedback. | Private |
| Withings | France | Withings SA is an online provider of digital health products and services to help people all over the world lead healthier, happier and more productive lives. | Private |
| Xsensio | Switzerland | Xsensio is a business to business service provider. They have developed the proprietary Lab-On-Skin sensing platform that senses real-time biochemical information from the surface of the skin. | Private |

Source: GlobalData © GlobalData

# 7 Glossary

Table 16: Glossary

| Term | Definition |
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| 3GPP | A standards organization composed of seven regional telecommunication associations as primary members ("organizational partners") and a variety of other organizations as associate members ("market representation partners"), which develops protocols for mobile telephony. |
| AI | Artificial intelligence, notably machine learning and the branch of computer science that aims to create it. |
| API (Application Programming Interface) | A set of functions and procedures allowing the creation of applications that access the features or data of an operating system, application, or other service. |
| Artificial Intelligence (AI) | Refers to software-based systems that use data inputs to make decisions on their own. |
| Augmented reality (AR) | Technology that allows the user to see the real world overlaid with a layer of digital content. This digital content layer can include sensor-based data, sound, video, graphics, or other datasets. |
| Baby Boomers | A demographic cohort that classifies people born between 1946 and 1964. |
| Big Data | Extremely large data sets that may be analyzed computationally to reveal patterns, trends, and associations, especially relating to human behavior and interactions. |
| Bluetooth Low Energy (BLE) | A wireless personal area network technology aimed at novel applications in the healthcare, fitness, beacons, security, and home entertainment industries. |
| Bot | Intelligence systems that can interact with end users via text through websites, short message service and other means to provide a service to users. For a health bot to become an established part of healthcare workflows, it must be defined how the health bot can provide value to user organizations. |
| Cloud computing | The provision of IT infrastructure, operating software, middleware and applications hosted within a data center and accessed by the end user via the Internet. |
| Conversational Platforms | Tools that employ a variety of technologies – including speech recognition, natural language processing (NLP), contextual awareness and machine learning – to enable human-like interaction with computer systems. |
| Data Privacy Impact Assessment (DPIA) | Refers to a process to facilitate identification and minimization of the data protection risks of a project. |
| Deep learning | A field of machine learning that is built using artificial neural networks, which model the way neurons in the human brain talk to each other. |
| Digitization | The cultural transformation of how disruptive technologies that provide digital and objective data accessible to both caregivers and patients leads to an equal level doctor-patient relationship with shared decision-making and the democratization of care |
| ECG | Electrocardiogram , or EKG, a test that measures the electrical activity of the heartbeat. With each beat, an electrical impulse (or “wave”) travels through the heart. |
| E-Ink displays | A type of electronic paper (e-paper) display technology, characterized by high visibility and contrast, a wide viewing angle and low power requirements. |
| Electrocardiogram | A record or display of a person's heartbeat produced by electrocardiography. |
| Ethernet | The technology that is most commonly used in wired local area networks (LANs) that connect computers and other electronic devices within a small geographical area. |
| Facial recognition | A way of recognizing a human face through technology. A facial recognition system uses biometrics to map facial features from a photograph or video. |
| FinTech | The technology and innovation that aims to compete with traditional financial methods in the delivery of financial services. |
| First person imaging | A graphical perspective rendered from the viewpoint of a person, or a viewpoint from the cockpit or front seat of a vehicle. |
| Galvanic skin response | A change in the electrical resistance of the skin caused by emotional stress, measurable with a sensitive galvanometer. |
| General Data Protection Regulation (GDPR) | A regulation in European Union (EU) law on data protection and privacy for all individuals within the EU and the European Economic Area (EEA). It also addresses the export of personal data outside the EU and EEA areas. |
| Generation X | The demographic cohort following the baby boomers and preceding the Millennials – classifies people born between early-to-mid 1960s to the early 1980s. |
| Generation Z | The demographic cohort after the Millennials – classifies people born between the mid-1990s to mid-2000s. |

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| Gyroscope | A device used for measuring or maintaining orientation and angular velocity. |
| Head mounted display (HMD) | A type of computer display device or monitor that is worn on the head or is built in as part of a helmet. |
| Health Insurance Portability and Accountability Act of 1996 (HIPAA) | An act under the US Federal Government that primarily aims to ease health insurance, protect the confidentiality and security of healthcare information, and help the healthcare industry control administrative costs. |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 (HIPAA) |
| Internet of Things (IoT) | The IoT is the network of physical devices, vehicles, home appliances, and other items embedded with electronics, software, sensors, actuators, and network connectivity that enable these objects to connect and exchange data. |
| Internet Protocol (IP) | The principal communications protocol for relaying datagrams across network boundaries |
| ISM Band | Represents the radio bands reserved internationally for the use of radio frequency energy for industrial, scientific and medical purposes other than telecommunications. |
| Ivory Tower | A state of privileged seclusion or separation from the facts and practicalities of the real world. |
| Latency | A term used to indicate any kind of delay that happens in data communication over a network. |
| Liquid Crystal Displays (LCDs) | A flat-panel display or other electronically modulated optical device that uses the light-modulating properties of liquid crystals. |
| Machine Learning (ML) | An application of AI that gives computer systems the ability to learn and improve from data without being explicitly programmed. Examples include predictive data models or software platforms that analyze behavioral data. |
| Millennials | The demographic cohort following Generation X and preceding Generation Z. The early 1980s is considered as starting birth years and the mid-1990s to early 2000s as ending birth years |
| Mixed reality (MR) | Refers to the merging of real and virtual worlds to produce new environments and visualizations where physical and digital objects co-exist and interact in real time. |
| Natural language processing (NLP) | A field of AI concerned with enabling computers to analyze, understand and derive meaning from human language (both text and speech). |
| Near Field Communication (NFC) | A set of communication protocols that enable two electronic devices to establish communication by bringing them within 4 cm (1.6 inches) of each other. |
| Network Centric Warfare (NCW) | A military doctrine that seeks to translate an information advantage into a competitive advantage through the robust computer networking of geographically dispersed forces. |
| OCR Chatbot | Advanced optical character recognition (OCR) or — rather more specific — handwriting recognition system that allows fonts and different styles of handwriting to be learned by a computer during processing to improve accuracy and recognition levels. |
| Original equipment manufacturer (OEM) | An original equipment manufacturer (OEM) is a company that produces parts and equipment that may be marketed by another manufacturer |
| Operating Systems (OS) | Refers to system software that manages computer hardware and software resources and provides common services for computer programs. |
| Organic light emitting diodes (OLEDs) | A light-emitting diode (LED) in which the emissive electroluminescent layer is a film of organic compound that emits light in response to an electric current. |
| Protected health information (PHI) | PHI under the US law is any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity and can be linked to a specific individual. |
| Proximity Marketing | Refers to the localized wireless distribution of advertising content associated with a particular place. |
| Proximity sensors | A sensor able to detect the presence of nearby objects without any physical contact. |
| Remote patient monitoring (RPM) | RPM is a subcategory of homecare telehealth that allows patients to use mobile medical devices and technology to gather patient-generated health data (PGHD) and send it to healthcare professionals. |
| Robots | Classic definition: A machine designed to execute one or more tasks repeatedly with speed and precision; Alternative definition: A physically embodied AI agent whose actions have effects on the physical world |
| SaaS | A method of software delivery and licensing in which software is accessed online via a subscription, rather than bought and installed on individual computers. |
| Say's Law of Markets | In classical economics, Say's law, or the law of markets, states that "Supply creates its own demand"[citation needed], the aggregate production necessarily precedes an equal quantity of aggregate demand |
| System-on-Chip (SoC) | An integrated circuit (IC) that typically include a central processing unit, memory, input/output ports and secondary storage – all on a coin sized microchip. |
| Systolic and diastolic pressure | Blood pressure where top number is the maximum pressure your heart exerts while beating (systolic pressure), and |

| | |
|---|---|
| | the bottom number is the amount of pressure in your arteries between beats (diastolic pressure). The numeric difference between your systolic and diastolic blood pressure is called your pulse pressure. |
| The Office for Civil Rights (OCR) | A sub-agency of the US Department of Education that is primarily focused on enforcing civil rights laws prohibiting schools from engaging in discrimination on the basis of race, color, national origin, sex, disability, age, or membership in patriotic youth organizations. |
| Universal Serial Bus (USB) | A common interface that enables communication between devices and a host controller such as a personal computer (PC). |
| Virtual personal assistant | A software agent that can perform tasks or services for an individual based on verbal commands. |
| Virtual reality (VR) | Technology that aims to immerse the user in an entirely artificial world, which has the illusion of reality. It uses special equipment such as a headset and gloves fitted with sensors to simulate a user's physical presence in a 3D environment. |
| WaaS | Wearables-as-a-service allow end users or institutions to “rent” the device and service. |
| Wireless Fidelity (Wi-Fi) | The popular wireless networking technology that uses radio waves to provide wireless high-speed Internet and network connections. |

Source: GlobalData

# 8 Appendix: Our "Thematic" Research Methodology

## 8.1 Traditional Thematic Research Does a Poor Job of Picking Winners and Losers

Thematic research is not just about picking the right themes, because themes do not operate in isolation. The difficulty in picking winners and losers in any industry arises from the sheer number of technology cycles that are currently in full swing. Most companies are impacted by multiple themes, many of which conflict with one another.

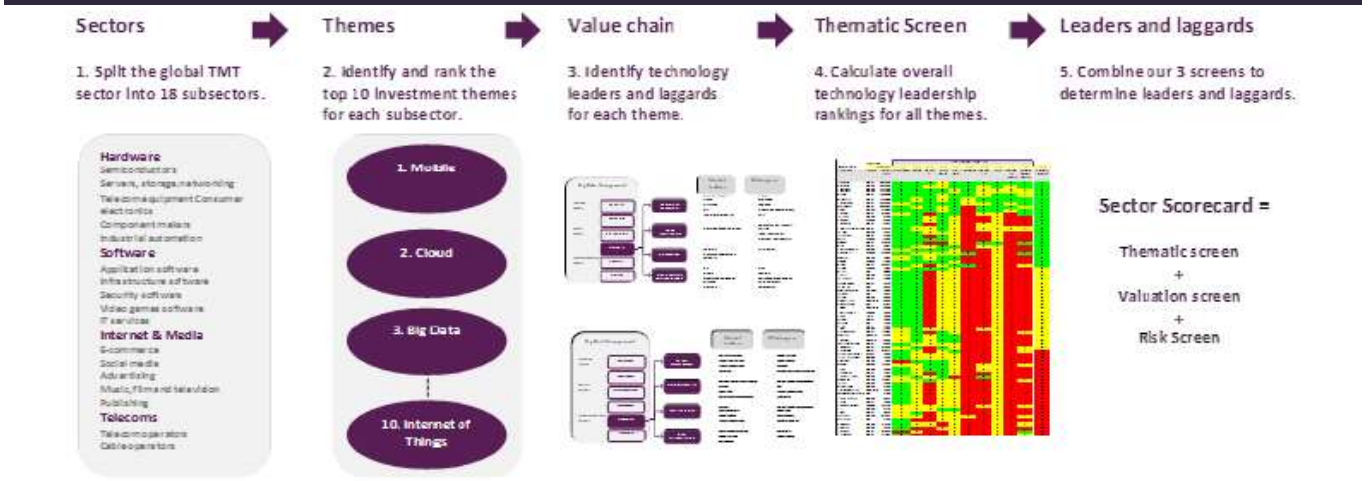
## 8.2 Introducing GlobalData's Thematic Engine

GlobalData has developed a unique thematic methodology for ranking technology, media, and telecom companies based on their relative strength in the big investment themes that are impacting their industry. Our thematic engine identifies which companies are best placed to succeed in a future filled with multiple disruptive threats. To do this, GlobalData track the performance of the top 600 technology, media, and telecom stocks against the 50 most important themes driving their earnings, generating 30,000 thematic scores. The algorithms in GlobalData's thematic engine help to clearly identify the longer-term winners and losers within the technology, media and telecoms (TMTs) sector.

## 8.3 This Is How It Works

First, we split the global TMT industry into 18 subsectors. Second, GlobalData splits and rank the top 10 themes for each subsector (these can be technology themes, macroeconomic themes, or regulatory themes). Third, GlobalData publishes in-depth research on specific themes, identifying the winners and losers. The problem is that companies are exposed to multiple investment themes. As such, our fourth step is to create a thematic screen for each sector to calculate overall technology leadership rankings after taking all themes impacting that sector into account. Finally, we combine this thematic screen with the valuation screen and a risk screen to generate a sector scorecard, which is then used to help assess overall winners and losers.

Figure 18: Five-Step Approach for Generating a Sector Scorecard




Source: GlobalData



Each sector scorecard has three screens:

- **The Thematic Screen** identifies the overall technology leaders in the 10 themes that matter most.
- **The Valuation Screen** identifies which players are the most attractively priced, relative to their peers.
- **The Risk Screen** identifies the riskiest players in each industry based on four categories: corporate governance risk, accounting risk, technology risk, and political risk.

## 8.4 How Our Research Reports Fit into Our Overall Research Methodology

We produce three tiers of thematic reports to help our clients identify winners and losers in their industry:

- **Single Theme:** These reports offer in-depth research into a specific theme (such as AI). They identify winners and losers based on technology leadership, market position, and other factors.
- **Multi-Theme:** These reports cover all stocks and all themes within a sector, giving readers a strong sense of how everything fits together and how conflicting themes might interact with one another.
- **Sector Scorecard:** Each sector scorecard has a thematic screen, a risk screen, and a valuation screen. Live scorecards for each of our 18 sectors are available on our client portal.

## 8.5 About GlobalData

4,000 of the world's largest companies make better and more timely decisions thanks to our unique data, expert analysis, and innovative solutions delivered through a single platform.

GlobalData is one of the world's leading providers of company operational data and strategic analysis, providing detailed information on tens of thousands of companies globally. Our highly qualified team of Analysts, Researchers, and Solution Consultants use proprietary data sources and various tools and techniques to gather, analyze, and represent the latest and most reliable information essential for businesses to sustain a competitive edge. Data are continuously updated and revised by large teams of research experts, so that they always reflect the latest events and information. With a large dedicated research and analysis capability, GlobalData employs rigorous primary and secondary research techniques in developing unique data sets and research material for this series and its other reports. GlobalData offers comprehensive geographic coverage across the world's most important sectors, focusing particularly on energy and healthcare.

## 8.6 Primary Research – KOLs Interviewed for This Report

### 8.6.1 KOLs

- **Rafael Grossman, MD, FACS and Clinical Advisor**

General, Trauma, Acute Care, Advanced Laparoscopic & Robotic Surgeon

EHMS (Northern Light) Health

Brewer, USA

Clinical/ Medical Advisor & Board Positions

Magic Leap Technologies; HealthCode.io; Curely; mHealth.org; Nuvium; Medical Realities; Carbone Health; ANIMA RES

Global

- **Bertalan Meskó, MD, PhD**

Director

The Medical Futurist Institute

Hungary

- **Sam Volchenboum, MD PhD**

Co-founder

Litmus Health

Chicago, USA

- **Undisclosed KOL, MD**

Guildford, UK

- **Undisclosed KOL, PhD**

London, UK

## 8.7 About the Authors

### 8.7.1 Digital Healthcare Analyst

**Roxanne Balfe, MSc** is a Digital Healthcare Analyst at GlobalData in London where she participates in digital analytics providing insights on strategy and digital offerings from pharma across disease areas and channels. Prior to joining GlobalData, Roxanne was a commercial manager at a start-up company within the Artificial Intelligence space, and previously worked for Chiesi Pharmaceuticals where she worked with a first to market product in respiratory (COPD and asthma) across primary and secondary care. Roxanne graduated from the University of Edinburgh with an MSc in Management of the Bioeconomy, Innovation, and Governance, and received a BSc with First Class Honors in Biomedical Sciences from Oxford Brookes University, spending 6 months as a research assistant in an oncogenomics laboratory in Italy researching microRNA expression in metastatic melanoma.

### 8.7.2 Medical Device Analyst

**Ashley Young, PhD**, is a Medical Device Analyst at GlobalData Healthcare with a focus on Neurology and Cardiology Devices. In her work, she collates information from primary participants, key opinion leaders, and secondary sources with real world data to analyze and forecast specific device markets across 39 different countries. Ashley has a PhD from University of Toronto, as well as a strong background in biology and expertise in health and medicine. Before joining GlobalData, Ashley worked in healthcare communications where she collaborated with industry experts, giving her a thorough understanding of medical regulatory frameworks and the Canadian healthcare system.

### 8.7.3 Senior Director, Market Research

**Urte Jakimaviciute, MSc,** is a director of market research in the healthcare division at GlobalData, London. Her primary responsibility includes managing the market research process for the syndicated reports portfolio and custom consulting projects. Urte has more than 10 years of experience in the market research industry; her experience is evenly split between qualitative and quantitative methodologies. Prior to GlobalData, she held management roles at market agencies providing consulting and market research services to the healthcare/technology industries. Urte holds a MS in Economics from the LUISS Guido Carli University, Italy.

### 8.7.4 Global Head and EVP of Healthcare Operations and Strategy

**Bornadata (Bonnie) Bain, PhD** is the Global Head and EVP of Healthcare Operations and Strategy. Bonnie has almost 20 years' experience in the healthcare sector and a proven track record of developing innovative solutions on both the client and agency sides of the business. Bonnie was GlobalData Healthcare's first western analyst and under her leadership, the company launched a number of premium syndicated reports, analytical tools and databases in the pharmaceuticals and medical devices space. Prior to GlobalData, Bonnie was Vice President and Global Research & Analysis Director for Informa's Pharma Division, which includes Datamonitor Healthcare, Scrip Group, and Business Insight. Bonnie also worked for several years at Decision Resources as an Analyst and Project Manager. On the client side of the industry, Bonnie worked for several years as a Senior Manager in Marketing Strategy and Analytics at Boston Scientific where her work contributed to the successful commercialization of the first ever Access and Visualization Platform at the company. Bonnie has a PhD in Biochemistry and Molecular Biology from Purdue University and completed a Post-Doctoral Fellowship in Molecular Pharmacology at the University Of Miami School Of Medicine. She also has a graduate certificate in Applied Management Principles from Purdue University Krannert School of Management.

## 8.8 Contact Us

If you have any more questions regarding our research, please contact us:

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## 8.9 Disclaimer



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