Health Wearables

TREND SCAN REPORT

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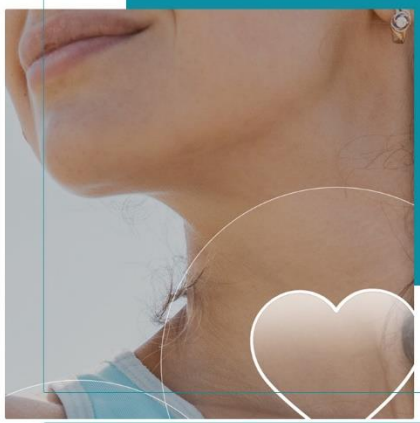

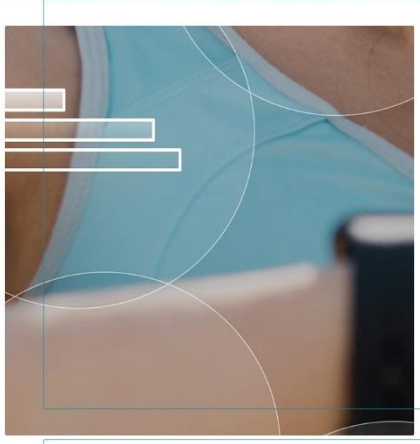

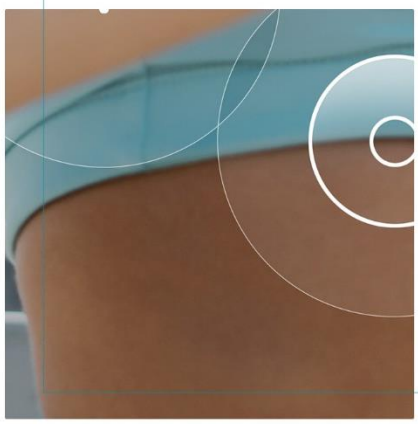

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Trend Scan – Wearables for Health Monitoring

I. Introduction & Market Outlook

A. Define Health Wearables

A health wearable is any device that is worn by a patient for the purpose of tracking real-time health metrics to communicate physiological data to a clinician for medical monitoring and corresponding treatment plans.

The Smartwatch is a widespread technology used primarily for convenience in communication, tracking of fitness goals, and entertainment. However, a growing market for health monitoring integrations and specialized clinical data collection via a smartwatch will expand the technical capabilities of these wearable devices. Modern Bluetooth and App-enabled smartwatches are robust, portable, unobtrusive, and relatively low cost to a consumer or enterprise, and are increasingly utilized for collecting biometric and time-elapsed health informatics from patients for their medical providers.

B. Importance of Developing Health Wearable Technologies

Wearable sensor technologies including smartwatches record and relay physiological data for telediagnosis, provide reliable fall detection, track movement, and log sleep patterns. Analyzed data from wearables can aid in the prevention of certain diseases and assist in the early recognition of health abnormalities. Heart rate, blood pressure, body temperature, breath rate, blood oxygen saturation, motion tracking, body composition, and other bio measurements can be effortlessly collected by an individual and/or remotely monitored by a healthcare provider.

As aging populations and life expectancies increase, active healthcare systems and consumers will demand cost-effective, convenient off-site solutions for monitoring vital signs. The expansion of consumer products in this space will also allow more people to become knowledgeable in their own health data (or that of a loved one) and better advocate for their existing health conditions or track their progress in a wellness improvement program.

Emerging technologies in health wearables can improve wellness program outcomes, provide important real-time medical information to patients who lack immediate access to healthcare facilities, and enhance patient-caregiver communication allowing better informed decisions for future care plans and medication management.

C. Market Outlook

The Wearable Medical Devices market was $25 billion USD in 2020 and is expected to grow over 22.9% through 2027.[1] By 2024, it has been predicted that nearly 440 million units of consumer health and wellness wearable devices will be available.[2] 43% of hospitals accept data from patient-owned wearable devices, a recent survey by HIMSS and AT&T found.[3]

The possibility of collecting important data through the widespread use of smartwatches is also an opportunity for the Healthcare industry to conduct large, remote, useful clinical trials at a lower cost.[4]

II. Current Technology of Wearables

A. Hardware & Software– Fitness Trackers, Smartwatches & other wearables for health monitoring

Consumer Device	Description/Function	Health Wearable URL	Software & Sensors
Apple Watch Series 3 – 6, Ultra	consumer smartwatch See Section B - Software	https://www.apple.com/healthcare/apple-watch/	Heart rate and irregular rhythm notifications, ECG app, and Atrial Fibrillation history recording[5] using the Apple Watch photoplethysmography sensor technology.[6]
Google, Fitbit, Pixel Watch Google > Fossil, Misfit Shine	Consumer fitness armbands & smartwatches	https://www.fitbit.com/global/us/technology https://www.mobihealthnews.com/content/google-pays-40m-fossil-mystery-smartwatch-tech-reportedly-misfit	Device Connect for Fitbit and Google Cloud with Cloud Healthcare API
Garmin	GPS smartwatch and fitness health wearable	https://www.garmin.com/en-US/garmin-technology/health-science/	Apps for maps, sports, diving/marine, aviation, health solutions; Health api, standard SDK, Companion SDK https://www.garmin.com/en-US/health/

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8546159/

[2] https://www2.deloitte.com/nl/nl/pages/technologie-media-telecom/articles/when-digital-tech-becomes-a-medical-device.html

[3] https://www.fiercehealthcare.com/tech/wearables-shift-from-fitness-to-clinical-use-samsung-smart-watch-can-monitor-blood-pressure

[4] https://www.nejm.org/doi/full/10.1056/NEJMoa1901183

[5] https://www.apple.com/healthcare/docs/site/Apple_Watch_Arrhythmia_Detection.pdf

[6] https://www.nejm.org/doi/full/10.1056/NEJMoa1901183

Samsung Galaxy Watch & Fit2	consumer fitness bands and smartwatches	https://www.samsung.com/us/watches/galaxy-watch5/#bioactive-sensor	https://www.samsung.com/ie/apps/samsung-health-monitor Samsung Health Monitor App
OnePulse & AT&T	Smartwatch See Section B - Software	https://www.wearable-technologies.com/2019/02/onelife-offering-att-lte-m-certified-health-monitoring-smartwatch-onepulse/	Mobile medical software and data collection using trackers, reminders and alert technologies for heart rate, location, movement and sleep with Bluetooth protocol to connect to other medical devices.
Oura	Fitness/sleep health ring	https://ouraring.com/business#section-integration	Gen3 Firmware Oura App https://support.ouraring.com/hc/en-us/articles/10471574315411-Gen3-Firmware-Updates
Whoop	fitness/sleep health wearable	https://www.whoop.com/	
Withings Pulse	Fitness/sleep health wearable	https://www.withings.com/us/en/pulse-hr	
Clinical Device	**Description/Function**	**Health Wearable URL**	
Axivity AX3	research/clinical level device (motion data)	https://axivity.com/product/ax3	
Biobeat	Vital monitoring, data collection tool	https://www.bio-beat.com/	
Movella Dot & (Xsens) MTw Awinda	research/clinical level device (motion tracker[7]) See Section B - Software	https://www.movella.com/products/wearables/movella-dot	MT Manager Software Suite provides real-time access to the output of the motion tracker data, enabling integration into other applications.

[7] https://www.xsens.com/hubfs/3446270/Downloads/Manuals/MTwAwinda_WhitePaper.pdf

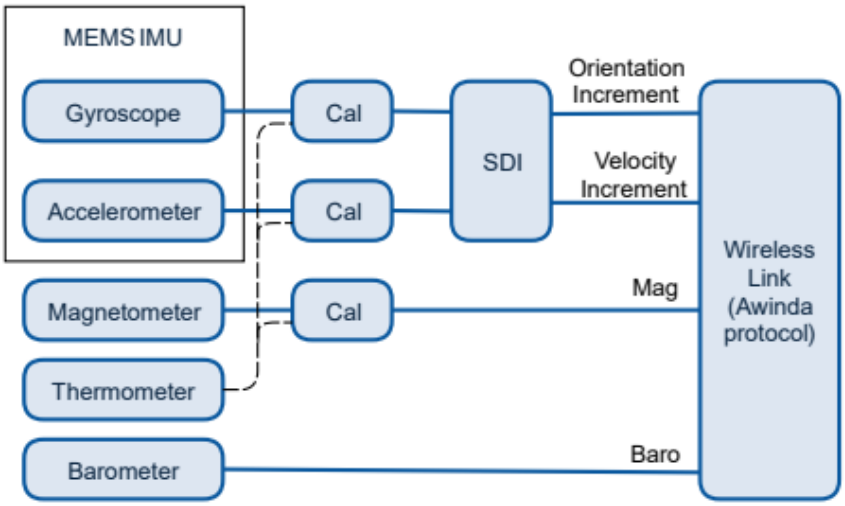

Figure 1: MTw Awinda Signal Processing Architecture

B. Top of Market smartwatches & other wearables

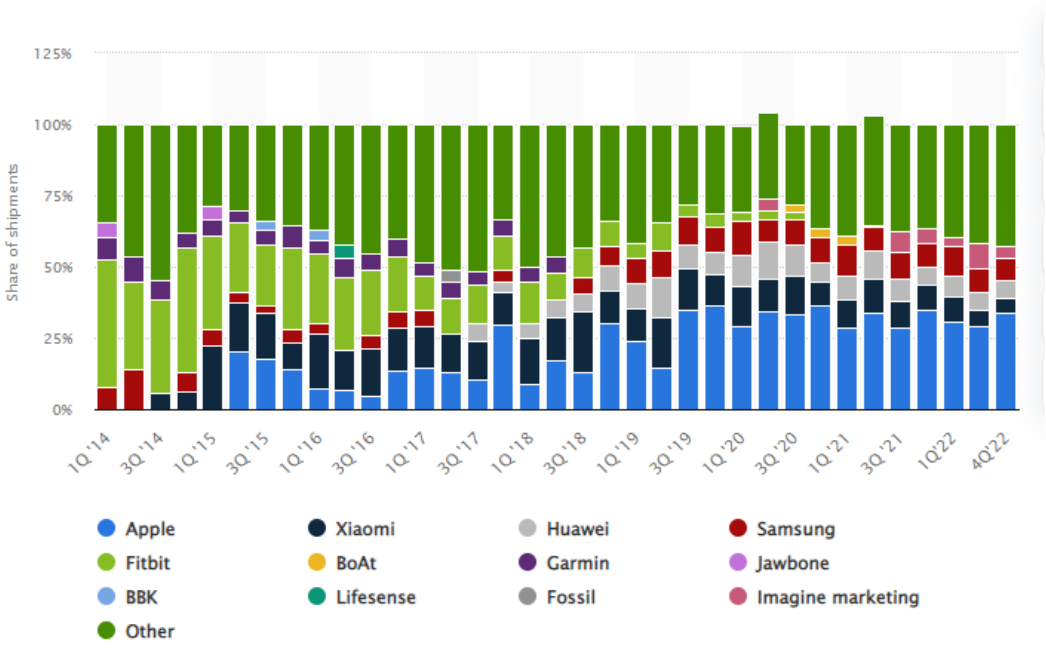

Figure 2: 2014-2022 Quarter 4 Wearables Market Share

Apple wearable units account for 33.6% of all wearable devices shipped in 4Q 2022. Xiaomi, a Chinese electronics company, is the 3rd largest vendor in the world for these products. Samsung, Huawei, and a variety of other companies are also entering the space, encompassing 42% of market share together. Fitbit, acquired by Google, is still another dominant brand which first created the wearables market with early technology fitness trackers.

C. Types of Sensors and Functionality

Not all wearables are built with the same functionalities. Early models incorporated step trackers and simple heart rate monitors. The Gyroscope, Accelerometer, Magnetometer, Thermometer, and Barometer are extensively utilized to collect important data in these medical wearables. Novel technologies in sensors are integrated successfully for innovative consumer products.

1) ECG Sensors – Electrocardiogram (ECG) technology to measure heart activity and reveal any abnormalities. A primary tool for physicians, cardiologists, and sports medicine professionals.

2) Motion Trackers and MEMS IMU Sensor Systems-
   Primarily for remote monitoring of elderly and disabled, fitness and movement data, physical and occupational therapist professionals. This technology would be important in Fall Risk Assessment and Fall Detection Devices[8], see Table 6 for a research project using the clinical device, Movella (XSens) MTw Awinda, though automated motion tracking via body-worn Inertial Measurement Units (IMUs) built into consumer smartwatches[9] was comparable to research-grade devices.

   Consequently, commercial use of MEMS sensors can be further explored in consumer Medical alert systems.

3) Electrochemical skin sensors provide continuous, non-invasive chemical and metabolic biomarkers including NutriTrek[10] smartwatch with a disposable sensor patch and an electrophoretic display. Bioelectronic patches could include the analysis of sweat in diabetes patients and other metabolic diseases or focus on pharmacokinetics and drug interactions and detection within the body.

4) Health Wearables on other parts of the body:
   Hearable Instruments (smart headphones[11]) and smart rings[12] as alternatives to wrist (smartwatch) for PPG monitoring or sleep tracking measurement

III. Applications of Wearable Electronics and Smartwatches in Healthcare

A. Vital monitoring: Tracking the bioactivity of patients (heartrate, respiration, blood oxygen levels) including stress management.

Over 30% of US adults have hypertension which requires frequent visits to a healthcare provider for recording and monitoring blood pressure. A program implemented to manage chronic disease patients

[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4166886/
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7766923/
[10] https://www.nature.com/articles/s41551-022-00916-z
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8546159/
[12] https://www.theverge.com/2023/3/15/23640205/oura-ring-sleep-tracking-chronotype-circadian-rhythm

with high blood pressure at Ochsner Health System[13] combined a home blood pressure cuff with a health wearable for physical activity monitoring to integrate with the electronic health record observed by a remote care team. Another example case for vascular health is the Hague's Haga Teaching Hospital in the Netherlands, a customer of the Device Connect for Fitbit.[14]

B. Activity monitoring: Wellness incentives for treatment plans and insurance savings. Examples include increased movement and activity (step counter, distance traveled, calories burned) and improved sleep

United Healthcare Motion program rewards participants who wear a Fitbit device to monitor progress on daily fitness and activity goals. Involvement reduces out-of-pocket medical expenses for corporate wellness program members and activity tends to increase with the accountability of a device monitoring engagement.[15] A similar collaboration exists between Aetna and Apple.

C. Elderly Care & Communication primarily during medical emergencies

Reviewed by the National Council on Aging as "the best "medical alert watches" of 2023: Medical Guardian MGMove, Bay Alarm Medical SOS Smartwatch, LifeStation SideKick Smart, Apple Watch, UnaliWear Kanega Watch, and HandsFree HealthWellBe Watch.

D. Data collection indicating early signs of disease

The Apple Watch demonstrates high levels of accuracy and is acceptable for continuous monitoring of motion, mobility, and heart biometrics like ECG. The Apple Heart Study[16] was conducted to identify pulse irregularity and cardiac arrhythmias of over 400,000 study participants to gauge accurate detection of undiagnosed AF (atrial fibrillation).

E. Post clinical care and remote clinical trials

A platform was developed to collect and manage health data for a study entitled "Predictive Monitoring in Person-Centered Care Using Smartwatches." The LIKA-Web platform was built to be scalable and suitable for multiple large-scale and long-term follow-up health monitoring studies to provide clinicians with a powerful tool to monitor remote patients. This study utilized Samsung Galaxy devices in unison with the Lika-App digital solution.[17]

F. Rehabilitation, physical and occupational therapy

A gait monitoring device using IMU sensors for Parkinson's disease patients experiencing intermittent inability to walk or turn direction, called FOG "Freezing of Gait." The study by Stanford University says patients preferred the wrist location for the wearable, however, the findings showed clinical data collection was more accurate for location at the ankle in this study.[18]

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[13] https://www.apple.com/healthcare/
[14] https://www.fiercehealthcare.com/health-tech/google-fitbit-launch-new-analytics-tools-help-hospitals-use-wearables-data
[15] https://www.aarp.org/home-family/personal-technology/info-2022/wearables-insurance.html
[16] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8099048/
[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9523529/
[18] https://cheme.stanford.edu/freezing-gait-assessment-gait-locations-using-wearables-parkinsons-disease-patients

G. Sports Medicine & fitness performance research[19]

Stanford researchers in the LPCH Motion and Gait Lab have also developed a sensor to wear on the golf course to analyze a player's biomechanical swing. Benchmarking professional golfers' motion data, a user can compare his real time rotational data to maximize club head speed in a golf swing and improve or adjust to prevent injury.[20]

IV. User Acceptance, Industry Usage, and Privacy

A recent survey from HIMSS and AT&T shows one third of hospitals currently provide wearables to post-op patients for health monitoring and as medical devices to supplement preventative care. This percentage increases to 47% of healthcare providers who provide patients with chronic diseases remote at-home monitoring via smartphone apps and smartwatches.[21]

Personal Healthcare Internet of Things (HIoT) has primarily been used by consumers for self-monitoring while Clinical HIoT was designed for use specifically under a physician's guidance. (Examples of adopted Clinical HIoT are smart glucose monitors and connected inhalers)[22] However, as medical providers incorporate more IoT in the clinical setting, patients can experience better care through increased responsiveness and customized care plans.

A. Factors influencing user adoption

Health Insurance Companies (Aetna and Humana) partner with wearable technology companies (Samsung, Apple) to empower patient accountability in self-health monitoring and to also encourage daily physical activity. Clinical use of the devices and the data it produces also fosters device adoption by an individual patient and gives incentives for its long-term use to positively impact a health outcome.

The Covid-19 pandemic also drove digital health wearables adoption, as patients were increasingly asked to refrain from in person visits to monitor non-life threatening, preexisting conditions. Interestingly, wearable devices were concurrently helping to detect early signs of virus infection via temperature rise, loss of sleep quality, and subtle changes in heart rate.[23]

The pandemic was also a stressful period which resulted in a need for self-management of subclinical mental health conditions (anxiety, depression, sleep disorders)[24] another segment of wellness monitoring to consider. Additional resources for evidence of the potential utility of wearables for self-

[19] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4702159/
[20] https://techfinder.stanford.edu/technology_detail.php?ID=44758
[21] https://www.fiercehealthcare.com/tech/wearables-shift-from-fitness-to-clinical-use-samsung-smart-watch-can-monitor-blood-pressure
[22] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7970885/
[23] https://www2.deloitte.com/nl/nl/pages/technologie-media-telecom/articles/when-digital-tech-becomes-a-medical-device.html
[24] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9916237/

reporting and monitoring mental health can be found in research by the eCareWell project and the UK Community Renewal Fund.[25]

The rising movement of using technology to monitor and aid physical, emotional, and mental wellbeing via apps are factors which will strengthen the adoption of these wearable devices to track related biometrics, especially as varying and diverse software is released and marketed to consumers focused on personal health and wellness. “Biohacking” and similar extreme fitness trends universally apply wearable devices for physically active individuals looking to quantify and qualify their progress toward a specific health goal.

B. Duration of use and user satisfaction

Surveys support that patients and providers administered wearables for health monitoring were engaged with the device and pleased with its unobtrusiveness, ease of use, personalized treatment outcomes, and promising healthcare functionalities.[26]

This research by the National Institute for Health Research, Imperial College London Biomedical Research Centre indicates healthcare professionals and their patients agree wearable motion sensors (such as: MTw Awinda, Axivity AX3, Apple Watch Series 3 and 5) are easy to use long term, comfortable to wear, and do not limit daily activities or cause user distress.

From a consumer standpoint, fitness trackers are gaining popularity as their technology catches up with the functionality of a smartwatch. The design and display features are constantly evolving for different fashion styles and battery life and ease of use are also advantageous for continuous wearing and good consumer reviews.[27] The popularity of the smartwatch in the market is a clear indication of human-centered design and likability. Although usually larger in size and requiring more frequent charging, a smartwatch has more functions and its data output more robust. Both styles are comfortable for most people to use when exercising or sleeping, tracking important health metrics 24 hours a day.

C. Privacy and Security expectations

eHealth data privacy is of utmost importance in the design and development of connected, wearable medical devices. There are challenges to address in unauthorized access and data disclosure, tampering, and forgery.[28] To enhance the governance of healthcare data sharing, transmission, and storage Health Insurance Portability and Accountability Act (HIPPA) and General Data Protection Regulation (GDPR) are in place to prevent and find solutions to security vulnerabilities between medical networks, cloud computing, and eHealth devices.[29]

[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9916237/
[26] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7766923/
[27] https://www.consumerreports.org/electronics-computers/fitness-trackers/
[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8465695/
[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8465695/

Network connected medical wearables operating wirelessly can be vulnerable to cyberattack, and it is required that manufacturers reduce cybersecurity risk to maintain safety and effectiveness of the device by following federal guidelines outlined in the quality system regulations (QSRs).[30]

System integration within the HIoT ecosystem will involve data aggregation and communication from a variety of sources, technology vendors, health platforms, and alternative sensors complicating data streaming, storage, and real-time analysis.[31] Standards for BioMeT (Biometric monitoring technologies) will need to be continuously updated and reviewed to ensure patient confidentiality and safety.

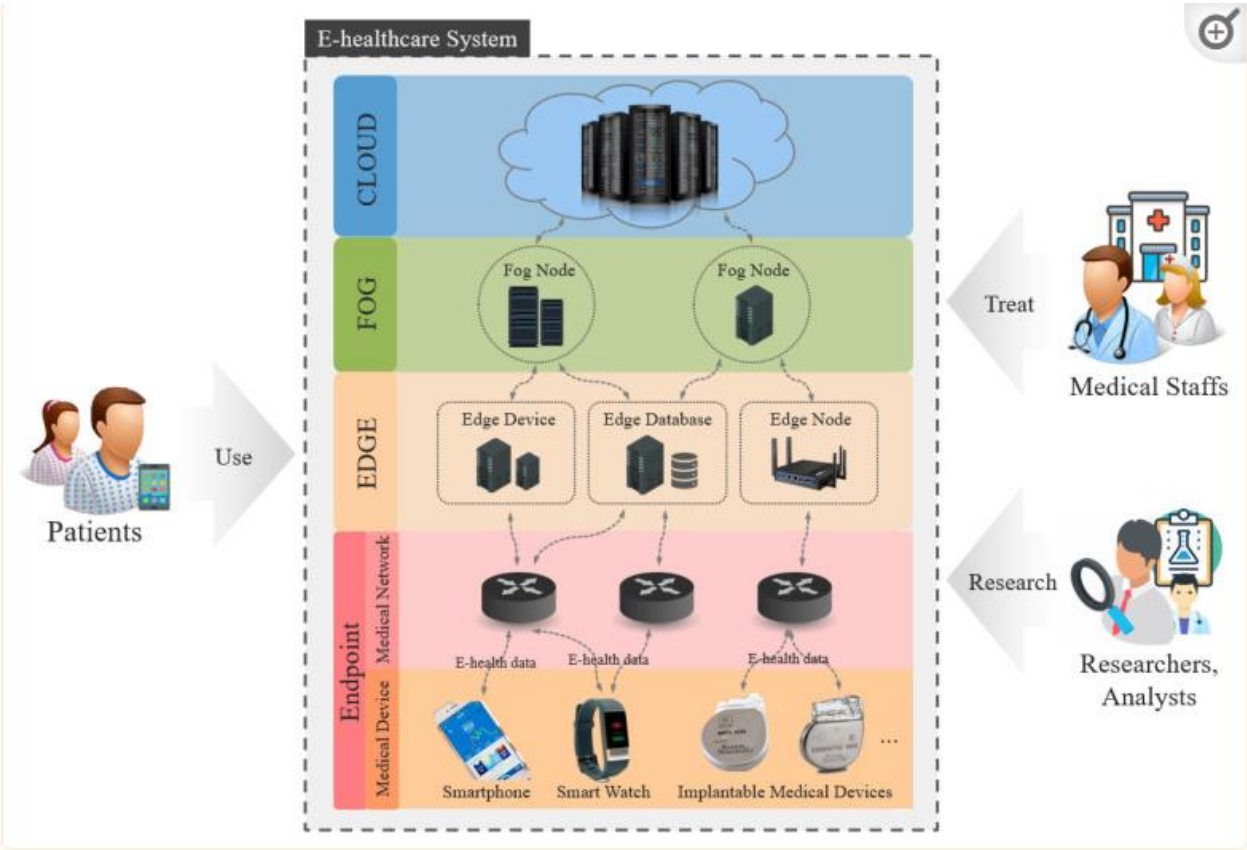

Figure 2: Overview of e-health system and the target domains

[30] https://www.fda.gov/media/123052/download

[31]

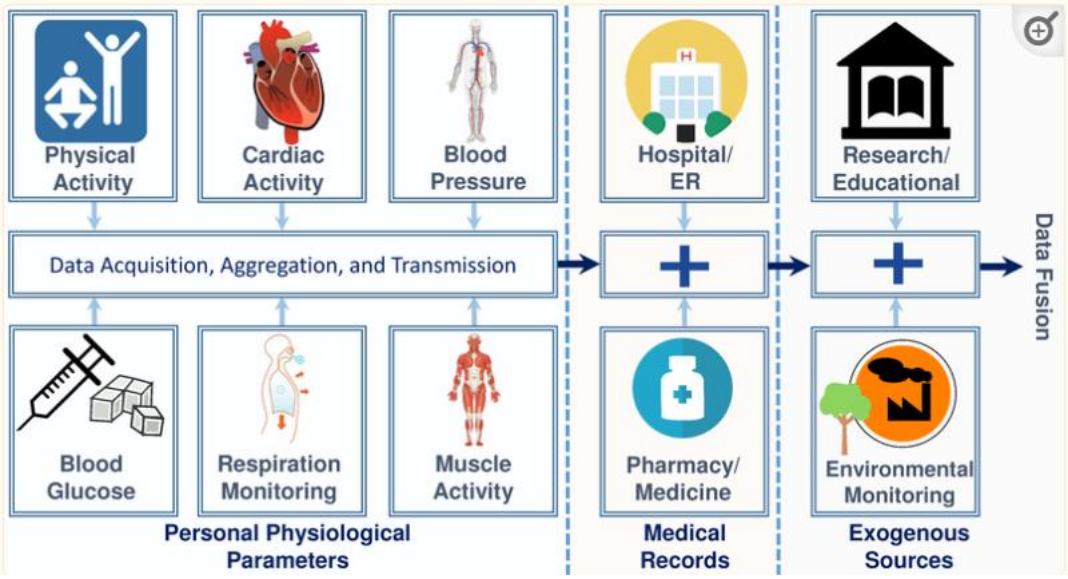

Figure 3: Modern smart healthcare applications are intricate multidimensional systems that not only focus on the personalized acquisition of physiological data but also incorporate information from various external sources such as past records of patients from their hospitals, research and educational resources, and even environmental information from smart city applications.[32]

D. Use Cases in Healthcare Professions

The entire field of healthcare utilizing these new technologies will expand with the market of medical wearables. Remote patient monitoring and management will increase and improve. Audiologists have innovated hearing aids through the years, but MedTech advances in bioelectronics and designs which incorporate simultaneous monitoring of other bio measurements from the ear canal[33] are obvious features to be engineered. Kinesiologists who study the movement of the body, particularly in physical and occupational therapies and prosthetics, have a range of wearable technology opportunities to track progress and improve mobility and pain management. Nurses and telehealth clinicians charged with patient care and monitoring vital signs are already quite familiar with wearables but will need additional on-going training as the hardware and software systems change and mature. Even pharmacists who serve as a knowledgeable resource outside of the hospital or doctor's office will be armed with wearable technology advice for ongoing patient care.[34]

[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7970885/
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8546159/
[34] https://www.edumed.org/spotlight/wearable-tech-smart-devices/

Successful implementation of wearable technology in future digital health systems and clinical processes should address the key features identified by a recent workshop by the National Institutes of Health's Big Data to Knowledge (BD2K) Centers of Excellence: The Mobilize Center at Stanford University and the Mobile-Sensor-to-Knowledge Center (MD2K).[35]

Figure 4: Listed here are the key features identified by the workgroup as responsible for success in digital health programs involving wearables.

V. Future Trends of Wearable Electronics and Smartwatches

[35] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7946921/

A. New technological advancements

MedTech innovation includes improvements in interface design, medical device comfort and fit, longer battery life and smaller battery size, as well as better integration of powerful management software.

Accurate health IoT data collection relies primarily on these technical capabilities:

(1) sensing, with a focus on miniaturization and power efficiency;
(2) communications, specifically standardized protocols, wireless connectivity, and availability of cloud infrastructure for all patient data;
(3) data analytics and extrapolation, using AI and machine learning to transform medical inferences from supplied biometrics.

Improvements in these technical areas enable robust individualized health care strategies which lead to better health outcomes and reductions in healthcare management costs.

B. Regulations

The FDA regulates medical devices via one of the three pathways: 510(k) clearance, De Novo review, or premarket approval (PMA).[36]
Regulatory framework for medical devices[37], both in vivo (metrics captured within the body, like heartrate) and in vitro diagnostics (IVD, biomarkers collected and analyzed outside the body from tissue, blood, saliva, urine, or sweat samples) are provided by the EU.[38]

During the Covid-19 public health emergency, the Food and Drug Administration issued an enforcement policy expanding the capabilities of health wearables to aid remote patient monitoring and reduce in clinic visits.[39] Since then the Digital Health Center of Excellence was established to coordinate entities working in the wearable technology space with FDA regulatory policies. Its purpose is to advance Software as a Medical Device (SaMD), wearables used as a medical device, and related technologies.

The FDA also issues guidance for compliance for low risk, "general wellness" products which promote a healthy lifestyle. Wearables fall into this product category when their intended use relates to:

- weight management
- physical fitness
- relaxation or stress management
- mental acuity
- self-esteem
- sleep management
- sexual function

[36] https://www.medrxiv.org/content/10.1101/2022.12.07.22283216v2
[37] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[38] https://eur-lex.europa.eu/eli/reg/2017/746/oj
[39] https://www.fda.gov/media/136290/download

Health wearables aid in daily positive wellness choices and monitor active lifestyles which reduce risks for chronic medical conditions including heart disease, high blood pressure, and type 2 diabetes. According to the Center for Devices and Radiological Health, a health wearable is a general wellness product that are medical devices for which the FDA does not intend to enforce regulations if it is not invasive, not implanted, and does not incorporate a technology that poses a risk to the safety of a user or other persons.[40]

VI. Conclusion

A. Summary of key findings

While there is already reputable competition in the health wearables market, Ezassi anticipates that there are innumerable applications across a variety of Biomed, Pharmaceutical research, Fashion/Apparel, and a multitude of other industries with unmet wireless, sensor technology data collection needs for health and motion monitoring. Creative and innovative partnerships across sectors will only support the growth and ubiquity of smartwatches and future versions of electronic health wearables.

Ezassi Innovation Software Topic Trends Analysis: Research, news articles, grants, and patents in this sector continue to be published as the technologies are modified, modernized, and miniaturized. The next phase of innovation will be affected by the latest in machine learning, engineering, and IoT.

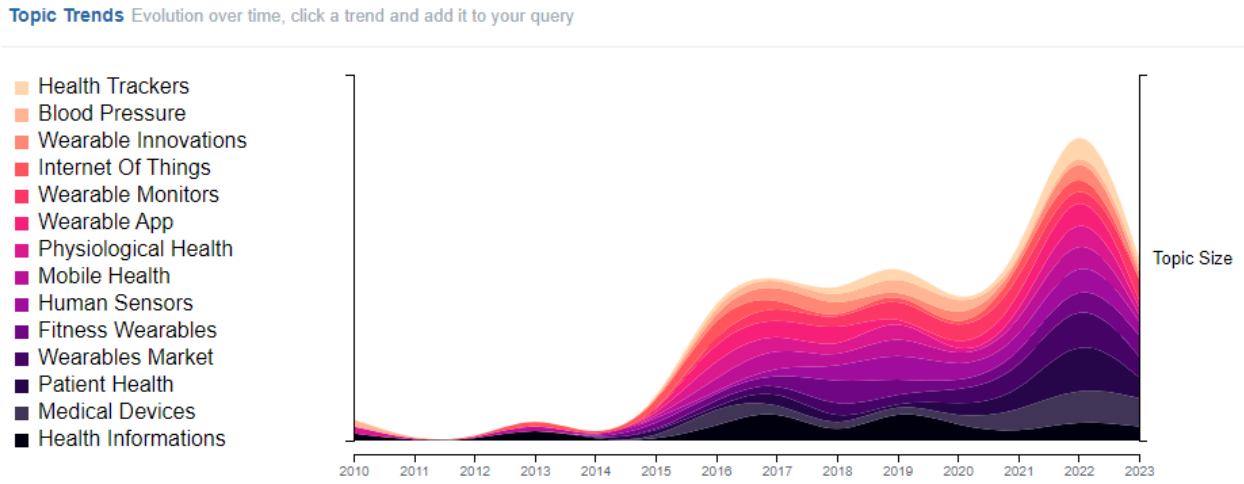

Figure 5: Topic Trends of health wearables 2010-2023, Ezassi Technology Scouting Software

[40] https://www.fda.gov/media/90652/download

Ezassi Commercial Readiness Level Analysis:
Health trackers and wearables for medical data collection and monitoring are ready for expanded markets and primed for company R&D authored publications validating their efficacy in healthcare use cases.

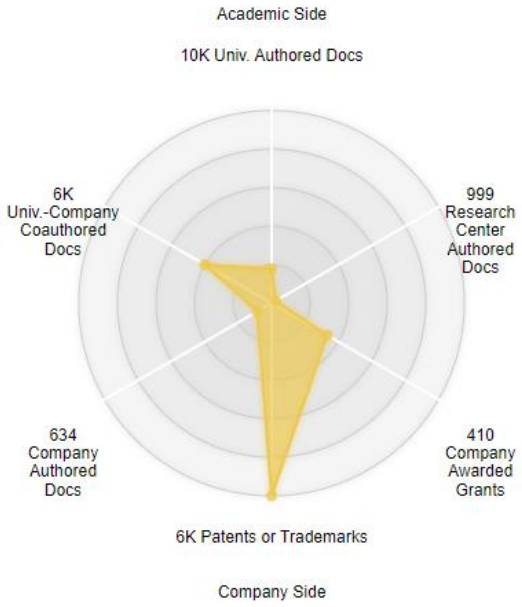

Figure 6: Commercial Readiness Level of health wearables 2010-2023,
Ezassi Technology Scouting Software

B. Suggestions for future investigations

Medical wearables which replace costly, time and labor intensive, routine diagnostic testing (blood draw, urine, biochemical and glucose tolerance tests) with electrochemical sensors based on carbon nanomaterials in detecting biomarkers of metabolic diseases[41]

Smart headphones, smart rings, smart clothing, and other innovative apparel ideas that utilize similar health sensor technologies but worn on different parts of the body other than the traditional wrist or arm location. Consequently, applications exist for new products that consider diverse body and skin types including infants, the disabled, or animals.

Another nascent technology is for wireless, stretchable hybrid electronics for ambulatory physiological monitoring attached directly to the skin.[42] Wearable biosensors which are lightweight, flexible, and in complete contact with the skin in a less obtrusive manner than a bulkier device are in development to measure sweat and interstitial fluids analysis.[43]

[41] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7432198/
[42] https://onlinelibrary.wiley.com/doi/10.1002/advs.201900939
[43] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7765261/

Improving the interface design, comfort fit, battery life and size, as well as better integration with powerful healthcare software will only grow the demand for bioelectronic wearables in the future. As the physical technology is engineered even smaller in scale, applications for communication with nanorobots and implantables are also possible.

Bioelectronic data analyzed and the new health treatments that result from this new research will continue to grow our complete understanding of the human body and will ultimately overlap and disrupt the field of pharmaceutical R&D.