Medical wearables: a critical evaluation of *innovations* and *strategic positioning* in modern healthcare

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Setting the context

In this point-of-view, **'Medical Wearables: A Critical Evaluation of Innovations and Strategic Positioning in Modern Healthcare'**, Capgemini Invent India's Life Sciences team explores the evolution and innovation journey of Medical Wearables that are connecting care across the wellness continuum, from general wellness to disease. The innovation journey of wearables has been marked by advancements in sensor technology, improvements in user experience and design, integration with artificial intelligence and health systems. The development and launch of medical-grade devices are driven by factors such as:

- **Technological** advancements with reduced size of sensors enabling more accurate tracking of vital signs. As the technology advanced, manufacturers integrated more sophisticated features for disease and health monitoring into their wearable devices.
- **Disease-related factors** such as rise of chronic diseases and an overall increase in global life expectancy has made way for more supportive care for patients and the elderly population.
- **Patient centricity** emphasizing the role of patients in the care continuum and the use of medical wearables for continuous monitoring, tracking of vital signs outside of traditional clinical setting is enabling self-management, thereby improving health outcomes and overall quality of life.

Setting the context

While medical wearables hold promise for personalizing decision-making and driving patient centricity, there have been setbacks and challenges questioning the long-term potential and impact of medical wearables. This point of view (PoV) critically evaluates the innovations in medical wearables by covering the following aspects:

1. **Understanding the Transition and Positioning of Medical Wearables:** Transitioning from consumer wearables to medical wearables involved several steps and considerations. We provide a context to this transition of consumer wearables and medical wearables, distinguishing between these two categories. This will help highlight how such devices are being positioned in the market.

2. **Landscaping of Medical Wearables:** Analyzing the landscape of medical wearables by examining a variety of devices that are currently available and in use. We provide a detailed analysis of twelve notable medical wearables to understand the application areas, helping consumers to understand the similarities and differences in use.

3. **Critical Evaluation of Medical Wearables:** Conducting a thorough evaluation and gap analysis of medical wearables by delving into each criterion including clinical, regulatory, technical criteria and user-experience. This will help in examining the current state and identifying areas that need improvement.

4. **History of the Future – Innovative Journey of Wearables in Diabetes and Cardiology:** The journey of wearables in managing diabetes and cardiology conditions showcases significant investments and technological advancements by the MedTech industry. This analysis highlights the evolution, achievements, and areas needing improvement in these domains.

We conclude the point-of-view by critically evaluating the benefits and challenges of medical wearables to provide a holistic view of this innovative and emerging space.

01

Understanding the transition and positioning of medical wearables

The global medical wearables are expected to grow at a CAGR of 14.6% by 2030 as per publicly available reports. Biowearables are an emerging category within medical wearables that are contributing to this growth. This section delves into the use of wearables for applications beyond fitness. The evolution of wearables from consumer-focused goals related to lifestyle and fitness applications to medical and healthcare applications represents a shift in the purpose and impact.

The evolution of wearables has witnessed a two-way transition highlighting the interplay between consumer and medical-focused application areas.

Scenario 1: Consumer to Medical applications – In this scenario, manufacturers first launched wearables with consumer-focused applications and then expanded their use to medical applications.

Scenario 2: Medical to Consumer applications – In this scenario, companies first targeted a therapeutic/disease area before expanding the use of wearables for the broader consumer community.

Medical Wearables

$33.85Bn (2023)
CAGR (2024-2030): 25.66%

Consumer Wearables

$71.91Bn (2023)
CAGR (2024-2030): 14.6%

Medical Bio wearables

$4.6Bn (2023)
CAGR (2024-2030): 7.19%

Market Size of Wearables (Grand View Research)

Wearables, not just a lifestyle accessory…

“Wearable technology” or “wearables” have for long been viewed as a lifestyle accessory targeting their premium activity trackers to fitness enthusiasts, athletes, etc. for general tracking of wellness, fitness or health activity.

An app that syncs to a wearable device and tracks daily fitness, health or wellbeing in general (like blood pressure, heart rate and rhythm, sleep, activity levels) rather than for a specific disease is not yet a medical wearable. Typically, these are non-invasive low-risk wearable devices used by consumers independently without any involvement of physicians. At this stage, the companies are not required to comply with regulatory approval requirements. Historically, the wearable devices have been considered low risk, not requiring a formal approval from regulatory bodies.

> The first category of general wellness intended uses involve claims about sustaining or offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions.
>
> The United States Food and Drug Administration (US FDA)

Consumer companies like Fitbit, Apple, and Garmin have over the decades tried to demonstrate how a consumer wearable moves beyond being a general wellness or fitness tracker and finds its use in clinical settings. Some of the consumer companies re-positioned themselves as medical devices companies (but not pure play medical device companies). The target users for the manufacturers evolved from the general population to patients, insurers, and hospitals delivering supportive needs for disease management. Devices or wearables making claims of diagnosis, monitoring, or treating medical conditions, fall under the purview of regulatory validation to meet the strict standards of safety, performance/effectiveness. The regulatory validation depends on factors such as:

- Existence of a predicate device that is already cleared or approved
- Risk- assessment/risks posed to patients.

As a result, such devices undergo the less intensive 501(k) clearance process, or the stricter Premarket Approval process in the United States of America (USA). Medical Wearables are entering the market after undergoing clinical trials and meeting regulatory requirements. While these devices may or may not always be prescribed by a physician/ health care professional (HCP), they aim at providing health value to users and medical grade data and insights to physicians/HCPs.

Wearables, less than medical care…

To ensure that the products meet the standards of a medical device, the companies are conducting validation studies to conform to user needs when used as intended. However, the lines between medical and non-medical use of wearable devices are still blurred. Medical wearables facilitate screening, diagnosis or treatment of a disease and do not make a medical claim yet.

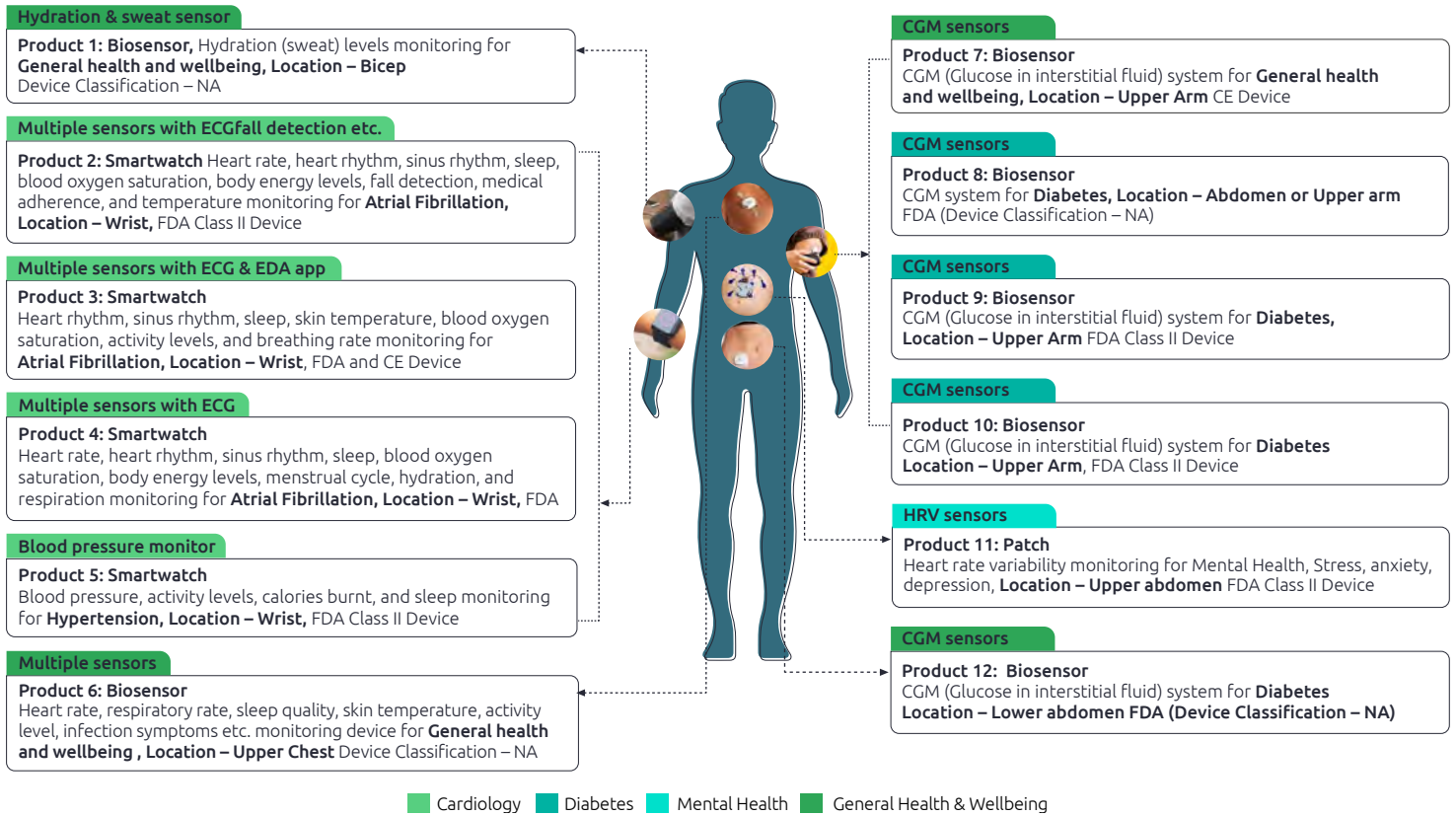
For example, the Fitbit Irregular Rhythm Notifications is a software-only mobile medical application, intended to be used with consumer wrist-worn products. The product helps in analyzing pulse rate data and identifying episodes of irregular heart rhythms suggestive of atrial fibrillation (Afib). Additionally, it provides a notification to the user.

The product is classified a Class II device, a Medical Wearable, only to supplement the decision of AFib screening along with user's risk factors and not to replace traditional methods of diagnosis or treatment. Human factors testing and a clinical study involving 225 subjects was conducted to establish the safety and effectiveness of the product. It was also compared to and is substantially equivalent to the predicate device.

The manufacturers of wearables state (on the packaging) that their products and services are not medical devices and are not intended to diagnose, treat, or prevent any disease. These are not intended to be equivalent to or replace scientific measurement devices or medical care.

02 Landscape of medical wearables

Capgemini Invent India's Life Sciences team conducted a label analysis of 12 marketed medical wearables in diabetes, mental health, and cardiological disease areas, and general wellness. This analysis could help in differentiating the use of medical wearables by their location, type of sensors used, and type of biomarkers measured, along with the regulatory classification of devices in the USA and the European Union (EU). The examples of medical wearables include continuous glucose monitoring (CGM) sensors, electrocardiogram (ECG) sensors, electronic skin patches, hydration and sweat sensors, photoplethysmography (PPG) sensors, smart glasses, head-mounted displays, smart clothing, etc.



Source: Capgemini Invent India's Life Sciences Team's Analysis of 12 marketed medical wearables

Note: *NA – Not available, CGM – Continuous glucose monitoring, ECG – Electrocardiogram, HRV – Heart rate variability*

This PoV provides a detailed analysis of 12 notable medical wearables to understand the application areas, helping consumers to understand the similarities and differences in use. A trend analysis of 12 marketed medical wearables was conducted to identify areas where medical wearables are being used, who is using it, and how it is being used.

Subset analysis of application areas of 12 marketed medical wearables

Disease-specific Solutions

33%

Focused on **Metabolic Disorders** i.e., Diabetes Disease Management

- All products are sensor based CGM (measurement of glucose in interstitial fluid).
- These wearables are placed in upper arm or abdomen area.
- For remote monitoring of persons with diabetes (PWD) outside of clinical settings.
- Prescription-based use.

33%

Focused on **Cardiological** therapy area (Hypertension and Atrial Fibrillation Disease Management)

- All products are software-only mobile medical application (majorly for measurement of heart rate and blood pressure).
- These are wrist-worn compatible wearables with sensors.
- For over-the-counter (OTC) use by general population (and not for patients with a diagnosed disease) interested in monitoring.

8%

Focused on **Neurological** therapy area (Mental Health)

- A smart patch is placed in the abdomen area.
- It's a prescription-based anxiety/ stress management tool.
- It's used for the measurement and improvement of heart rate variability (HRV, a gold standard biomarker for mental health) in patients with anxiety or depression or mental health symptoms.

Disease-agnostic Solutions

25%

Focused on **General Health and Well-being** (disease-agnostic)

- 50% of products for general health and well-being are sensor-based consumer wearables (these include the first and only biosensor to provide endurance to athletes with personalized hydration data).
- The remaining 50% are consumer bio wearables – these have expanded the use of sensing technology for diabetes to general population looking to manage their weight, sleep, energy, and thoughts.

Capgemini Invent India's Life Sciences team's analysis of 12 marketed medical wearables

03

Critical evaluation of medical wearables

Products	Parameters for Assessment					
	Clinical Evidence	Regulatory Device Classification	Reimbursement Status	Technological Advancements	Reporting	Real-World Evidence
P1 (Biosensor)	1	1	1	3	1	1
P2 (Smartwatch)	3	3	1	3	3	1
P3 (Smartwatch)	3	3	1	3	3	1
P4 (Smartwatch)	3	2	1	2	2	1
P5 (Smartwatch)	2	3	1	2	2	1
P6 (Biosensor)	3	2	2	3	3	1
P7 (Biosensor)	1	2	1	2	2	1
P8 (Biosensor)	2	3	2	2	3	1
P9 (Biosensor)	2	3	3	2	3	3
P10 (Biosensor)	3	3	2	3	3	1
P11 (Biosensor)	2	2	2	3	2	1
P12 (Biosensor)	2	3	1	1	1	3

Capgemini Invent India's Life Sciences team's analysis of 12 marketed medical wearables using their own Scoring and Ranking Model

Note: Red color = low score of 1, yellow=moderate score of 2, green color= high score of 3; P=product

This section compares and analyzes 12 medical wearables across six parameters of – clinical evidence, regulatory consideration, reimbursement status, technological advancements, reporting and availability of real-world evidence. This will help in examining the current state and identifying areas that need improvement.

1. **Clinical Evidence:** Around 80% (10/12) of the wearables analyzed were clinically validated by at least one randomized clinical trial (RCT) before being granted a marketing approval from regulatory bodies. General wellness and cardiology wearables such as smartwatches conducted massive RCTs with recruitment numbers reaching 500 people. Additionally, 90% (11/12) of the wearables analyzed have been approved for at least two indications. About 60% (6/10) of the wearables have been approved for use among consumers over 18 years of age and the remaining 40% (4/10) can be used by consumers below the age of 18. For example, 25% (3/12) wearables (namely P9, P10, P11) are CGM systems that are approved for patients as young as four years old.

2. **Regulatory Device Classification:** In the EU and USA, regulatory approval for medical wearables is given according to European Medical Device Regulation and Medical Device Amendments of the United States (US) Food, Drug and Cosmetic Act, respectively. Around 60% (7/12) of the wearable products accessed were classified as FDA Class II devices and CE marked (CE implies "Conformité Européenne", meaning European conformity in French). The remaining 33% (4/12) are currently being marketed in only the USA or the EU while seeking regulatory approval in other markets.
Based on the analysis by Capgemini Invent India's Life Sciences team, it can be ascertained that a majority of the medical wearables are undergoing clinical trials and regulatory validation processes before entering the market. Most marketed medical wearables are focused on the therapy area, thus targeting one or two indications at the time of launch.

3. **Reimbursement Status:** Among the 12 wearables assessed, around 60% (7/12) were not reimbursed or reimbursable.

   These products are generally utilized for tracking health vitals and improving the health and fitness of consumers. The remaining 40% (5/12) of the wearables, designed for specific indications/diseases areas such as diabetes, mental health, and remote monitoring of patients in a hospital setting, are eligible for reimbursement in accordance with the respective country's national healthcare policy and framework.

4. **Technological Advancements:** Parameters such as sensor invasiveness, multi-modal compatibility, sensor life, health vitals tracking, and predictive analytics were evaluated. Around 60% (7/12) of the wearables assessed were completely non-invasive and predominantly designed for general health and fitness.

   The remaining 40% (5/12) were minimally invasive and CGM systems. About 65% (8/12) of the wearables are also designed to passively track health vitals such as heart rate and interstitial blood glucose and send alerts. For instance, a wearable used for remote patient monitoring can track almost 1000 biomarkers. Electronic sensors and patches are reusable and have an average battery life of 15-20 hours. Non-reusable sensors, usually minimally invasive, need to be changed consistently after 7-15 days. The quality of user experience with wearables hinges on several factors such as the comfort and convenience of wearing them, minimal invasiveness, and the presence of predictive alerts. According to a recent Capgemini Research Institute report,[1] 60% of consumers surveyed feel connected products such as health wearables/trackers help them to maintain and improve the state of their health, and there is a notable shift towards prioritizing health wearables, suggesting an increasing emphasis on personal safety, well-being, and the integration of technology into daily life. [1]

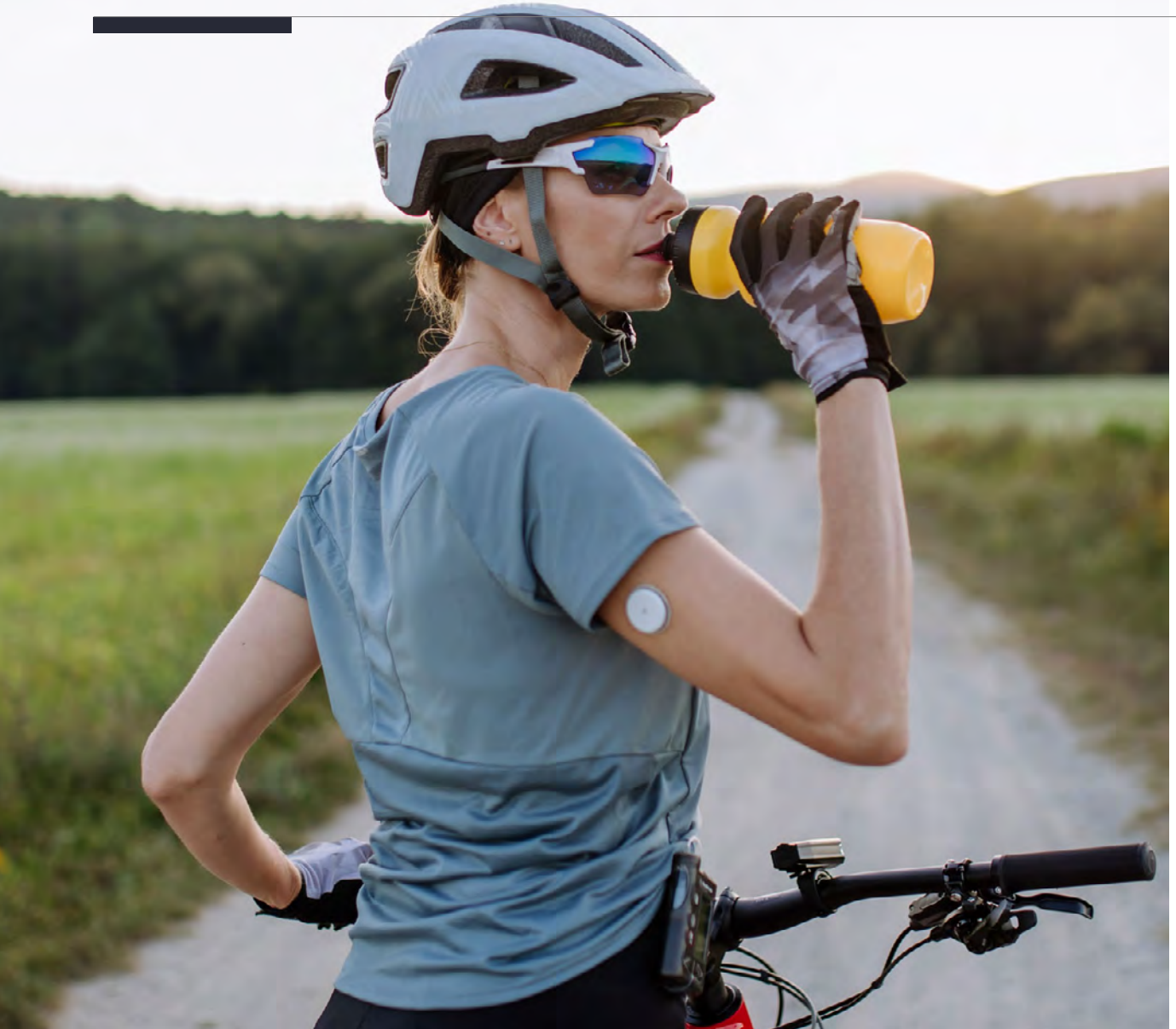
5. **Reporting:** About 50% (6/12) of the products analyzed, passively track health vitals at regular intervals to generate automatic reports in case of anomalies or emergencies, with users being able to access, review, and share these reports with their health care teams via a dedicated smartphone and/or smartwatch app. Health emergencies and anomalies are flagged, and consumers are alerted immediately. In CGM systems, this is seen

through an extensive system of Hyper and Hypoglycemic alerts, sometimes 60 minutes in advance. Remaining 50% wearables differed in the user interface, and the number and type of reports that were generated. A positive user experience with medical wearables, particularly concerning reporting features relies on adherence to data compliance standards and the provision of real-time reporting including emergency alerts to facilitate improved engagement with HCPs.

6. **Real-World Evidence:** Around 80% (10/12) of the wearable manufacturers did not conduct or sponsor a real-world evidence study. RCTs are already conducted for obtaining regulatory approval and manufacturers need to continuously update their products to meet safety requirements.

   The devices are advancing in technology, moving from non-invasive to minimally invasive devices and biowearables esp. in diabetes care. Generation of real-time reports is beneficial for users. However, the reimbursement of such devices needs more attention. Reimbursement can vary based on factors such as the type of device, target indication, country of approval, etc. Real-world studies demonstrating long-term evidence on the use of such devices remain an area of unmet need.

04 Innovations in wearables for diabetes and cardiology



Incremental innovation, characterized by continuous improvements and iterations, plays a significant role in enhancing the performance, usability, and acceptance of medical wearables. The innovation journey of medical wearables directly impacts patient care and outcomes in diabetes and cardiology. According to a recent Capgemini Research Institute study[1], most consumers surveyed (74%) are willing to upgrade their health wearables based on the price of the newer model and life span of current version. Consumer electronic companies like Apple, Fitbit and pure play medical devices companies like Abbott and Medtronic have iteratively improved their wearable devices to better serve the needs of users and healthcare providers.

Case 1: innovation in diabetes

Capgemini Invent India's Life Sciences team's analysis to understand the innovation of wearables / medical wearables over time in the area of diabetes therapy

This section includes Capgemini Invent India's Life Sciences team's analysis of the innovation journey of wearables in the area of diabetes therapy. In diabetes, the development of CGM system, including a biosensor, glucose monitoring, and insulin delivery, took its first significant step in patient monitoring. The table includes examples of wearable devices of leading medical device manufacturers. Innovation scores have been assigned based on Capgemini Invent India's Life Sciences team's analysis including factors like advancements in technology, reduced time for patient monitoring, reduced size of sensors, and improved patient convenience such as reduced need of calibration and fingerstick, improved user convenience and connected care with providers

Wearable innovations: A snapshot of recent advancements in the market

Company	Marketed Products	Launch Year	Therapy Area	Target User	Biomarker Measured	Regulatory Status	Prescribed by HCPs	Innovation Score
1. Dexcom	G7	2022	Diabetes	>2 years PWD	Glucose in interstitial fluid	FDA Class II CE	Yes	Highest
2. Medtronic	Guardian™ Connect system (Guardian Sensor 3)	2018	Diabetes	>14 years PWD	Glucose in interstitial fluid	FDA (PMA) CE	Yes	2nd Highest
3. Abbott	Libre 3	2022	Diabetes	>4 years PWD	Glucose in interstitial fluid	FDA Class II CE	Yes	3rd Highest

Size of bubble denotes Diabetes products revenue for 2023.

1. **Dexcom is a success story of technological advancements and innovation spanning more than a decade.** It is a medium size **CGM manufacturer by revenue** and it has been at the forefront of innovation developing the first real-time integrated CGM system, Dexcom STS (Short Term Sensor) in 2006. The technological advancements moved from a scenario where patients wore the devices for three days and needed a receiver to view their blood glucose levels to a scenario where patients could continuously monitor them for seven days. In 2016, Dexcom G5 was launched, and it became the first CGM system where patients could view blood glucose reports on smartphones. Subsequently, Dexcom G6 had better sensors that could be inserted by patients themselves with no calibration or fingerstick; it was the first FDA-approved CGM system that could be integrated with automated insulin dosing (AID) systems. **In 2022, Dexcom G7 was launched as the most accurate CGM system to date.** It boasted of a 60% smaller all-in-one sensor and transmitter compared to previous versions. The warmup time was reduced to just 30 minutes, and it was 75% faster than previous sensors. The G7 label was expanded for use in more than 2-year-old Type 1 & 2 diabetes patients and pregnant women as compared to previous versions. It remains the only CGM system compatible with an Apple watch.

2. **Medtronic launched the first continuous glucose management (CGM) system in 1999.** In 2011, the company launched Enlite with significant design improvements such as pain-free insertion, 69% reduction in volume compared to previous sensors and improved detection of hypoglycemia. The Enlite sensor was also labelled to use in multiple CGM and CGM plus Insulin pump systems to generate glucose readings every five minutes. However, the data was only available to HCPs after six days for retrospective blood glucose analysis. The company made significant improvements on its Guardian CGM systems, including real time alerts and expanded label for younger than 18-year-old patients. **In 2018, the breakthrough smart technology – Guardian™ Connect CGM System entered the market.** It consisted of Medtronic's most accurate sensor (Guardian Sensor 3), Guardian™ Link transmitter and Guardian Connect app. Blood glucose levels are measured every five minutes and shared with patients in real time via smartphones. Additionally, the CGM System can accurately predict hypo- and hyperglycemic episodes earlier than some of the other CGM systems in the market.

3. **Abbott, one of the largest in revenue size, launched advanced versions of sensor-based glucose monitoring system** – the FreeStyle Libre CGM family – over a timeline of a decade. In 2014, the FreeStyle Libre system was first launched in Europe with a 14-day wear time for adults with diabetes. It was the first-in-class to eliminate the need for fingerstick. Innovative versions of Libre were launched in Europe and USA over time. Each of these systems are compatible with their respective apps but the **Freestyle Libre 3 sensor launched in 2022 is the world's smallest and most discreet biosensor.** In the pipeline is Lingo which signifies a shift in Abbott's approach from medical wearables in diabetes to a new category of consumer wearables called Lingo.

Wearable innovations: A snapshot of recent advancements in the market

Company	Marketed Products	Launch Year	Therapy Area	Target User	Biomarker Measured	Regulatory Status	Prescribed by HCPs	Innovation Score
Apple	Apple series 9	2023	• Cardiology • General health and wellbeing	>22 years	• Heart rate • Heart rhythm • Sinus Rhythm	FDA Class II CE	No	Highest
Fitbit	Charge 6	2023				FDA Class II CE	No	2nd Highest
Garmin	Venu 3	2023				FDA Class II CE	No	3rd Highest
Fitbit	Sense 2	2022				FDA Class II CE	No	4th Highest
Omron	Heart Guide	2018	• Cardiology	>18 years	• Blood pressure • Activity levels • Calories burnt • Sleep	FDA Class II CE	No	5th Highest

**Only the devices with ECG app /similar features have been considered in the study*

Case 2: Innovation in Cardiology

Capgemini Invent India's Life Sciences team's analysis to understand the innovation of wearables / medical wearables over time in the area of cardiology therapy

In cardiology, ECG and blood pressure monitoring are the primary cardiovascular measurements that can be performed remotely by patients who are at high risk of cardiac issues or fitness enthusiasts in general. The table below includes examples of wearable devices of leading medical device manufacturers in the area of cardiological diseases. Innovation scores have been assigned based on Capgemini Invent India's Life Sciences team's analysis including factors like advancements in technology (such as improved heart rate sensors and heart rate monitoring, continuous ECG monitoring through ECG app, non-invasive blood pressure monitoring) among other benefits of connected care from providers.

1. **Garmin**, launched its first Venu product range in 2019; it was aimed at balancing smartwatch capabilities with fitness tracking. Garmin added the ECG app in the subsequent Venu 2 plus launched in 2022; it received FDA clearance in 2023. The technological advancements include improved heart rate sensors, more accurate biometric readings, advanced fitness and recovery features like sleep coaching, and nap detection. Additionally, ECG feature is also available in Garmin Fenix Pro, Epix Pro, Tactix 7, Venu3/3S series.

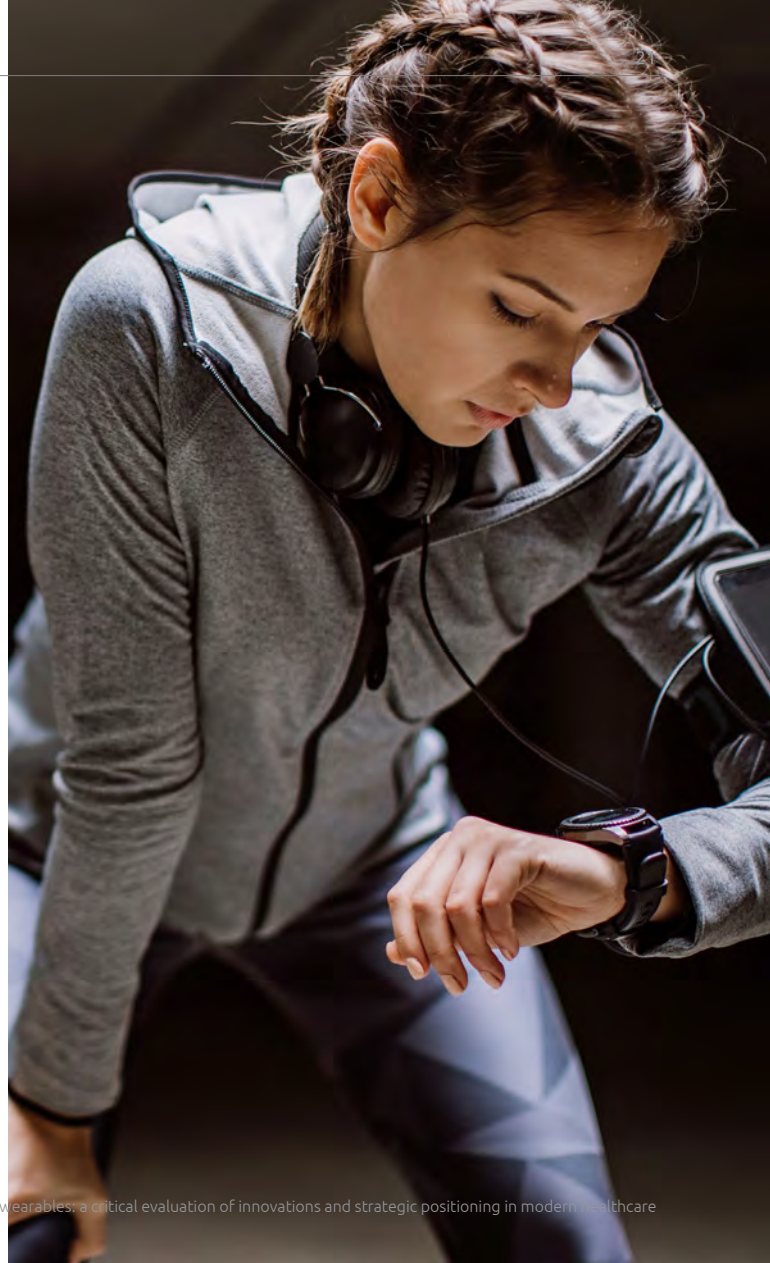
2. **Omron's** HeartGuide, launched in 2018, is the first clinically accurate, wearable blood pressure monitor designed in the innovative form of a wristwatch and is registered with the US FDA as a medical device. Along with a companion app, OMRON connect US/CAN, HeartGuide delivers powerful new technology that makes tracking and managing blood pressure easier than before – a step forward in wearable technology.

3. **Fitbit** personalized fitness tracking and it made several advancements since its inception in 2007. The journey began with Fitbit Classic, a clip-on tracker, which evolved into several advanced versions such as wristband, smartwatches, bangle, and pendant like Charge, Sense, Versa, etc.

The consecutive iterations integrated optical heart rate monitors, offering automatic and continuous heart rate tracking, along with oxygen saturation (SpO2) sensors. However, Fitbit Charge Series made a major leap in 2021 with the introduction of Charge 5 that featured an electrodermal activity (EDA) sensor and FDA-approved ECG app. Along with the fitness tracking advancements, all new versions had new technological features.

For example, Charge 6 launched in 2023 can be used as an external heart rate monitor on third-party fitness equipment – it can be connected to Peloton, NordicTrack, and Tonal equipment, thus offering a 60% more accurate heart rate sensor. Fitbit Sense launched in 2020 was the most advanced Fitbit product. In 2022, Fitbit Sense 2 replaced the older sensor with a new continuous electrodermal activity (cEDA) monitor that can consistently measure your stress levels throughout the day.

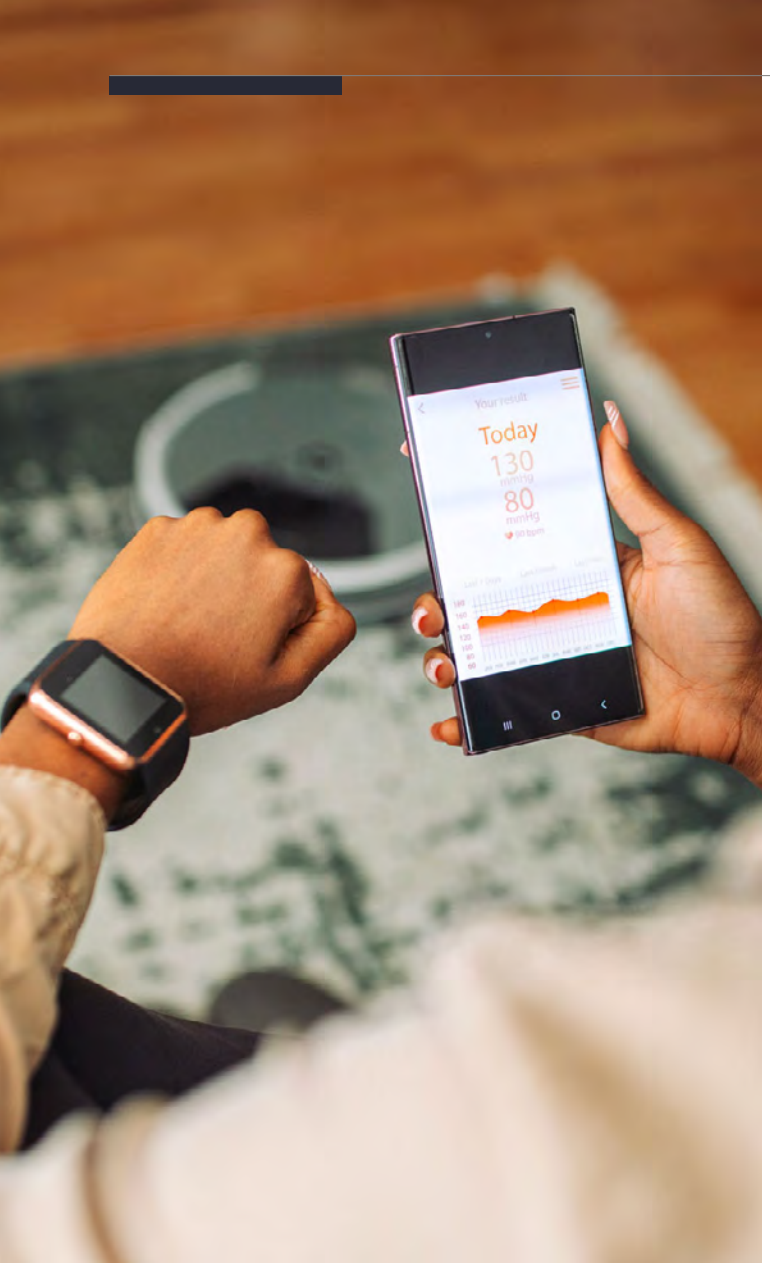
4. **Apple**, has made continuous advancements in its smartwatch offering. Apple launched its first series (Series 1) of smartwatches in 2016 with the heart rate sensor feature, followed by more technological advancements in Series 2. In 2017, Apple unveiled Series 3 with an optical heart sensor, global positioning system



(GPS) capabilities for heart rate monitoring, notifications for irregular rhythms and low cardio fitness, thereby making significant progress. In 2018, it became the first consumer wearables company to launch an ECG feature in its Series 4 watch, but it lacked an optical heart sensor to detect SpO2. This feature was later enhanced.

Apple Watch Series 8 launched in 2022 had an array of new features like body temperature sensor, improved crash detection, always-on display, faster charging, a larger screen with a standard English-language computer keyboard on which the first six letters of the second row are q, w, e, r, t, and y (QWERTY keyboard), the ability to take an ECG from wrist, SpO2, and a compass. Each new series surpassed its predecessor in terms of features. In 2023, Series 9 offered doubled peak brightness of the smart watch dial with a 30% performance boost over the previous-generation chip.

Understanding the innovation journey helps stakeholders assess the competitive landscape and comprehend the market positioning of different companies in the medical wearables space. Companies that invest in innovation and continuously improve their products are better positioned to meet evolving user needs and stay ahead of competitors.



Capgemini Invent India's life sciences team's position

Medical wearables are indeed a complex proposition; there are myriad uncertainties and challenges in this domain. Here are our takeaways in this scenario.

1. **Convergence of wearables in biopharma:** Medical wearables were considered as medical devices a few years back, as their primary use was as remote monitoring devices; over the years with digital therapeutics, combination products, digital wellness, and digital companions, the usage of medical wearables (along with digital applications by biopharma companies to monitor, deliver, coach, educate patients) has become widespread.

   Biopharma companies have invested in medical wearables and digital health applications for disease management and to provide patient support in care; and wearables are an integral role in a biopharma's go-to-market initiatives in decentralized clinical trials, real world evidence, patient support programs/patient engagement, HCP-patient engagement, post market surveillance etc. The ongoing shift towards emphasis on preventive care will further lead to the evolution of wearables into bio wearables for monitoring body parameters that are precursors to disease conditions.

2. **Realization of potential:** The medical wearables space was thriving during and post COVID-19 especially to remotely monitor chronic lifestyle diseases as patients were off-limits to healthcare providers. Post COVID-19, the enthusiasm it had created in HCPs and patients alike is fading away leading to an abrupt slowdown in funding of digital health companies. The funding winter impacted startups severely as innovative products could not pass the lifecycle to make it to the market; and the ones that had been commercialized faced a multitude of challenges including a lack of adoption by physicians and a lack of reimbursement.

   Largely the notion that digital health products such as wearables will have a high stickiness post COVID was proved incorrect as healthcare moved to pre-COVID

ways of working while retaining only a few applications for going digital and remote. Medical wearables are concentrated in chronic and lifestyle diseases such as diabetes and cardiac diseases; disease areas such as oncology and neonatal etc. have great potential.

The shortage in healthcare staff and the lack of healthcare infrastructure additionally provide an impetus to utilization of medical wearables in diagnosis and post treatment pathways in the patient journey.

3. **The journey from product development to commercialization** of medical wearables is full of uncertainty as product design, product-market fit, clinical trials, regulatory approvals, reimbursement, and physician and payer engagement are hurdles that a digital health product has to navigate before commercial success; and the commercialization pathways for medical wearables are still forming and will take few years to mature.

Capgemini supports Life Sciences clients with the following services:

- Intelligent Customer Interactions for Life sciences
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- Next-Gen Labs
- Smart Factory for Life Sciences
- Intelligent Supply Chain for Life Sciences
- Intelligent QA & Regulatory for Pharma
- Digital Core for Life Sciences

Appendix:

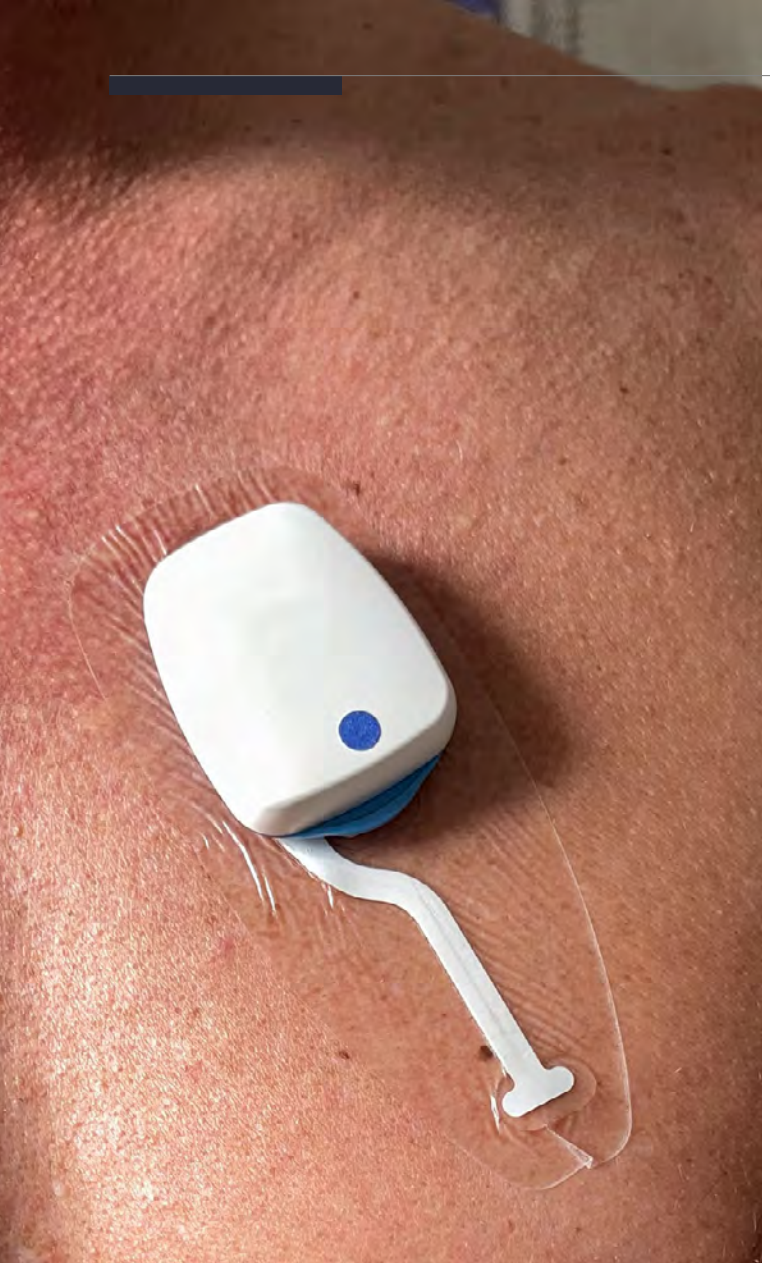
Methodology

12 Medical Wearables (namely Nix, Apple watch, Fitbit sense, Garmin Venu 2 Plus, Omron HeartGuide™, BioButton®, Abbott Libre Sense, Medtronic Guardian™ Connect system, Abbott Freestyle Libre 3, Dexcom G7, Lief Rx, and Medtronic iPro2 CGM System) have been analyzed through publicly available information and literature review.

Parameters for Impact Assessment i.e., Scoring and Benchmarking DTx Solutions:

Impact Assessment was conducted for all 12 Wearables included in our subset of analysis. The solutions were scored and benchmarked against a common broader evaluation criterion. Scoring criteria were pre-defined as outlined in the table.

Scoring Scale	Clinical Evidence	Regulatory Device Classification	Reimbursement Status	Technological Advancements	Reporting	Real-World Evidence (RWE)
3 (High)	At least 1 RCT done; No, of participants >100; Indications for use >3; No contraindications	Device classification or premarket approval (PMA) provided by two major regulatory bodies i.e., the FDA (USA) and CE (EU)	Reimbursed in USA and EU countries; Reimbursed in at least 2 countries	Non-invasive; Compatible with 3 or more modalities (reader, app and/or smartwatch); >14-day Sensor life; <= 30-minute sensor warm up time; Passive tracking and Predictive alerts	Automatic reporting in case of emergencies and anomalies; >3 Data reports generated; HCP and consumer facing; Health vitals reporting every minute or continuously	1 or more RWE studies completed with positive clinical validation
2 (Moderate)	At least 1 RCT done; No. of participants 100 or less; 2-3 Indications for use; 1-3 contraindications	Device classification or PMA provided by either one of the two regulatory bodies i.e., FDA (USA) or CE (EU)	Reimbursed either in USA or EU countries; Reimbursed in at least 1 country	Minimally invasive; Compatible with 2 or more modalities (reader, app and/or smartwatch); 7-14-day sensor life; 30-60-minute sensor warm up time; Passive tracking and Real-time alerts	No reporting in case of emergencies and anomalies; 2-3 Data reports generated; HCP or consumer-facing data reporting; Health vitals reporting every 5 minutes	At least one clinical RWE study underway
1 (Low)	No RCT data available	Not approved; Emergency and special approval; seeking approval by FDA (USA) or CE (EU)	Currently not reimbursable and/or seeking reimbursement approval in USA or EU countries	Minimally invasive; Compatible with only 1 modality (reader, app and/or smartwatch); <=7-day sensor life; >= 60-minute sensor warm-up time; No alerts	No reporting in case of emergencies and anomalies; Only 1 Data report generated; HCP or consumer-facing; No real-time reporting	No data on clinical RWE studies available



Biomarkers tracked by the 12 medical wearables

Reference; P=products

- P1: 3 (fluid loss, electrolyte loss, and sweat composition)
- P2: 2 (ECGs and irregular heartbeat events)
- P3: 2 (ECGs and irregular heartbeat events)
- P4: 1 (ECGs)
- P5: 2 (BP and Pulse rate)
- P6: >100
- P7: 3 (Glucose levels, trends, and metrics)
- P8: 4 (Current glucose value, current glucose trend, graph with recent trends, and user-entered events)
- P9: 4 (Current glucose value, current glucose trend, graph with recent glucose history, and user-entered events)
- P10: 4 (Current glucose value, current glucose trend, graph with recent glucose history, and user-entered events)
- P11: 2 (HRV and Beats-per-minute data in real time)
- P12: 1 (Blood glucose)

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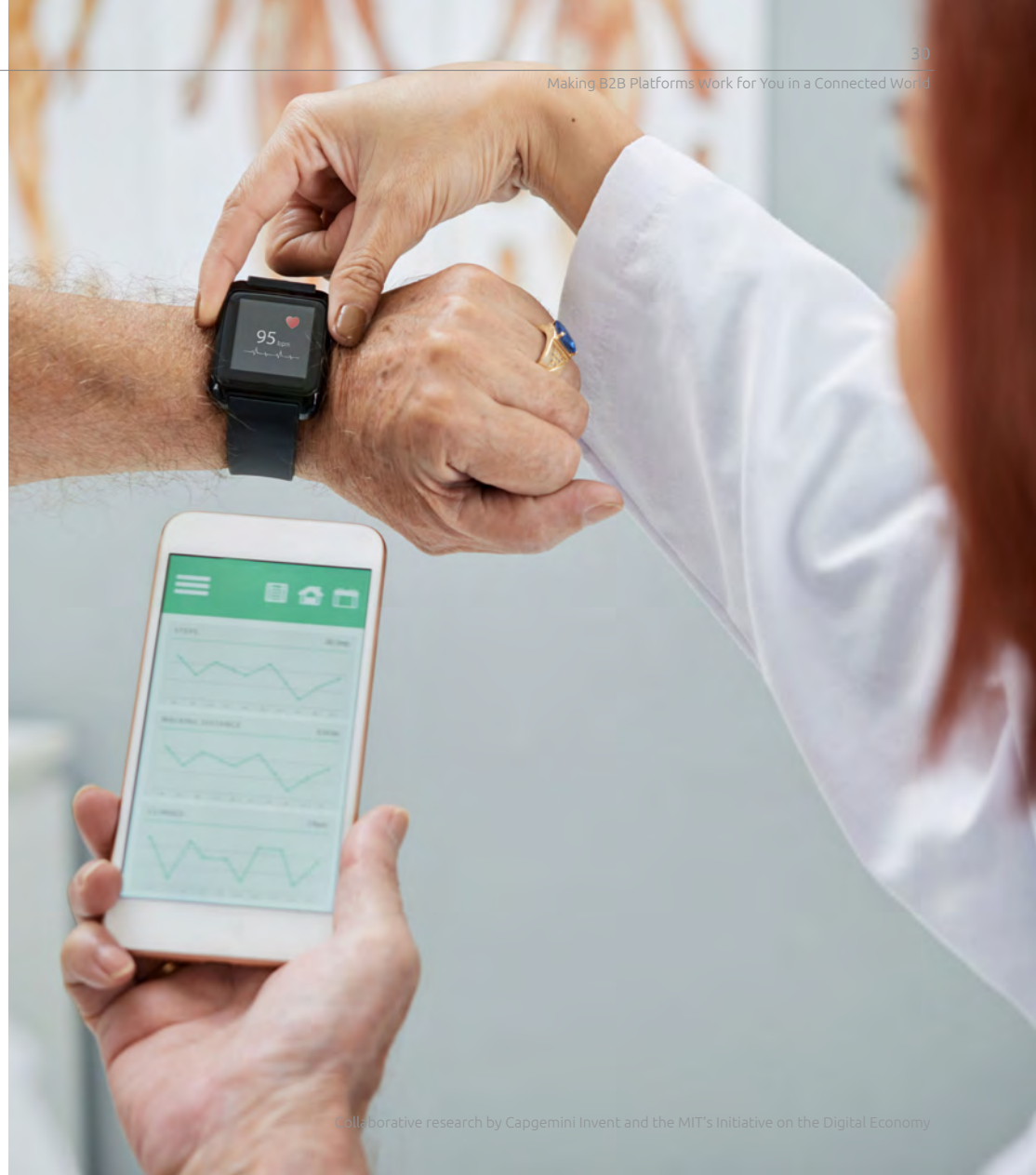

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