Beyond Fitbit:
Trends and Healthcare Policy Considerations for the Cognitive Internet of Things

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Executive summary

Recent advances in the Internet of Things (IoT) coupled with the rise of cloud and artificial intelligence technology are set to shake up the healthcare sector. Wearable technology shows exceptional promise for companies to collect and analyze massive amounts of biometric and other data.

This report examines market trends, regulatory framework and opportunities for cognitive technologies for three wearable markets: the United States, Japan and Germany. The following is a summary of our findings.

United States

The following market trends have been identified in the United States:

- Businesses are moving away from wrist devices and integrating devices onto other parts of the body, apparel, and fabric itself.
- Many people are willing to use home monitoring devices but the market has not yet gained sufficient consumer trust.
- Smart patches, ingestible devices and other devices for the hospital setting are starting to be used.

Major legal and regulatory considerations in the United States include:

- Low-risk general wellness devices such as fitness wearable devices are normally not subject to regulation by the FDA.
- The Health Insurance and Portability and Accountability Act (HIPAA) requires covered entities and business associates (BAs) to ensure the privacy and security of personally identifying health-related data.
- Data collected through wearable devices is protected by HIPAA only when it is shared with HIPAA covered entities such as hospitals.
- Recently, US regulatory bodies started taking a closer look at loose, weak regulations surrounding healthcare wearables.

Japan

The following market trends have been identified in Japan:

- A high percentage of wearable device users show concerns about leakage or misuse of sensitive data collected.
- The market has low penetration of fitness wearables.
- Due to an aging population, a large market potential exists for home monitoring devices.
- Clinical-grade wearables are increasing in presence.

Major legal and regulatory considerations in Japan include:

- Low-risk software is excluded from medical device regulation.

- The Act on Protection of Personal Information regulates handling of personal information in all industries.
- Some information including medical history is categorized as sensitive information and subject to greater level of protection.
- An amendment to the Act provides new legal obligations for handling sensitive information and establishes a new regulatory authority.

Germany

The following market trends have been identified in Germany:

- Germany's healthcare and medical technology market substantially consists of small and medium-sized enterprises.
- The mobile health segment is projected to reach EUR 3 billion in 2017 with fitness wearable devices driving revenue.
- Demand in mobile health solutions is driven by a large aging population and the growth of chronic diseases, which create an environment for the use of remote monitoring devices.

Major legal and regulatory considerations in Germany include:

- Manufacturers of medical devices must obtain a "CE" marking after conformity assessment before putting a device on the EU market.
- In 2016, the EU tightened regulations surrounding software as a medical device.
- German data protection laws require security specifications and consent before collecting and using personally identifiable information.

Recommendations

1. **Prioritize partnerships with US wearable device companies.** The US leads the markets in terms of number of users and startup device companies with artificial intelligence and data analytics. In comparison, Germany and Japan experience lower rates of wearable usage.

2. **Choose relationships with companies that diligently anonymize data and/or obtain consent from users to collect and share data.** Regulations in all three markets prohibit the transfer of personally identifiable data without consent. Anonymized data appear to be less regulated and avoids ethical issues where consent is explicitly provided. Working with device companies that have a high level of commitment to transparency and ethical standards will safeguard IBM's reputation.

3. **Among specific wearable device categories, continue to survey the developments of home monitoring devices in the US, Germany and Japan**. All three markets have significant populations that suffer from

chronic diseases. In Germany and Japan, the high rates of aging populations will drive this device market forward.

4. **Explore opportunities with platforms or cloud services that collect data from multiple wearable devices.** As technology in wearable devices advances and the number of wearable devices increases in the coming years, more types of data are expected to be collected. Platforms or cloud services that can collect data from these various devices and analyze such data together may provide better predictive analytics capabilities.

5. **For clinical devices, identify hospitals in markets that have incorporated or tested wearable devices into their healthcare system to use as case studies for IBM and potential partnerships.** Given the higher regulatory hurdles and system integration issues for clinical wearables, the rate of acceptance and usage in the clinical setting is expected to lag behind fitness and home monitoring wearable devices. However, these devices can provide significant cost-savings for hospitals in the future as technology improves and is eventually adopted. Some early case studies in the US can show some of the advantages.

6. **In the US, keep a close watch on the market performance and consumer feedback of home heart monitoring devices**. Chronic disease management for cardiovascular diseases is a widespread need but consumer trust is a market challenge that needs to be overcome for devices to become more mainstream.

7. **In the US, seek partnerships with startup companies that manufacturer fitness wearable devices for amateur and professional athletes or sports federations.** While the market for fitness wearable devices remains uncertain for the general population, opportunities for growth exist for the sports world. Athletes and coaches seek out the newest devices with artificial intelligence and real-time personal coaching capabilities that provide a competitive edge. This could be a growth area for other markets with competitive sports and as long as they are not categorized as "medical devices," they will be less regulated as fitness wearables.

8. **Be aware of potential changes to US regulation that could apply stronger requirements for wearable devices.** Currently, there are gray areas in US regulations that allow wearable device companies to avoid some privacy and security requirements found, for example, in HIPAA. However, as devices become more commonplace and extract more sensitive health-related data, these regulations may change as they have in Germany and Japan.

9. **Be aware of Japanese new data privacy regulations, going into effect in May 2017.** The new regulations include establishment of new regulatory authority, legal obligation for handling sensitive information,

and clarification of standards for anonymization. It remains unclear how these new regulations will be enforced and, therefore, how businesses subject to the regulations will be affected.

10. **In Germany, be aware of recent regulatory changes under the EU have made the transatlantic transfer of personal data more difficult.** In light of these developments in data privacy laws, caution is recommended when accessing data from EU residents to ensure strict compliance with new requirements.

Introduction
Background
Recent advances in the Internet of Things (IoT) coupled with the rise of cloud and artificial intelligence technology are set to shake up the healthcare sector. Wearable technology, especially devices that can connect to the Internet via a mobile application, show exceptional promise for companies to collect and analyze massive amounts of biometric and other data.

Since the early 2000s when wearable technology focused on fitness with the advent of *Fitbit* and other devices, the market has grown and new opportunities have emerged. According to the International Data Corporation (IDC), the global wearables market reached an all-time high with shipments reaching 33.9 million units shipped in the final quarter of 2016, an increase of 16.9% from the previous year.[i] Shipments for the entire year increased 25% with a yearly total of 104 million devices.[ii] The wearables market is expected to maintain growth due to the number of new vendors entering the market.[iii]

At the same time, the rise of wearable technology has created novel regulatory challenges and concerns over safety as well as data privacy and security. These concerns are elevated in the healthcare context given the expected expansion of integration of these devices that collect sensitive information.

Objectives
This report examines the current state of the market, the legal framework applicable to relevant technologies, and implications and potential impact of wearable devices and cognitive technology in healthcare. It then aims to make recommendations for IBM on how it can further advance its cognitive technology in combination with wearable devices in the fitness and healthcare sectors.

Scope and definition
This report focuses on three markets of interest to IBM: the United States, Germany, and Japan with emphasis on wearable devices, especially those that can pair with a mobile phone application. For purposes of this report, the term "wearable device" means electronics worn on or ingested in the body and that have the capacity to connect to the Internet through a mobile phone or otherwise to collect and transmit data. Wearables analysis in this report will mainly focus on three types of devices: fitness, consumer home monitoring, and devices intended for the clinical or hospital setting.

Methodology
The research and analysis in this report is based on a variety of primary and secondary sources including legal and regulatory documents; statistical data; interviews with industry experts, academia, and medical practitioners; newspaper articles; and industry websites, reports, and surveys.

Cross-country comparison
Current state of market
Healthcare wearable market growing 29.9% annually

The global healthcare wearable devices market earned $5.1 billion and is expected to reach $18.9 billion in 2020, at a compound annual growth rate (CAGR) of 29.9%. Among the different categories, consumer health wearables, including fitness and consumer remote monitoring devices are expected to grow at a CAGR of 27.8%. Medical and clinical-grade wearables are expected to grow at a CAGR of 32.9%, according to new analysis from Frost & Sullivan. [iv]

Two major trends are common across three markets:

- The emergence of "wearables 2.0" is shifting the landscape from stand-alone devices to lifestyle-enhancing systems tying together multiple connected devices and cloud services.

- Wristwear has dominated and driven market growth so far, but the smart clothing and sportswear categories are expected to expand in terms of wearables offerings with major participants such as Google and Levi's entering the market.

Consumer understanding and willingness to use varies

A larger percentage of consumers in the US and German markets have better understanding of wearable devices than those in Japan. Less willingness to use wearables in Japan may be due to less familiarity. However, the willingness to use wearables is also low in Germany despite consumers' better understanding of wearable devices (Exhibit 1).

Exhibit 1: Consumer perception of wearable devices

JAPAN — Willingness to use: 41%, Level of understanding: 49%
GERMANY — Willingness to use: 41%, Level of understanding: 74%
US — Willingness to use: 58%, Level of understanding: 87%

Legend: ■ Willingness to use   ■ Level of understanding
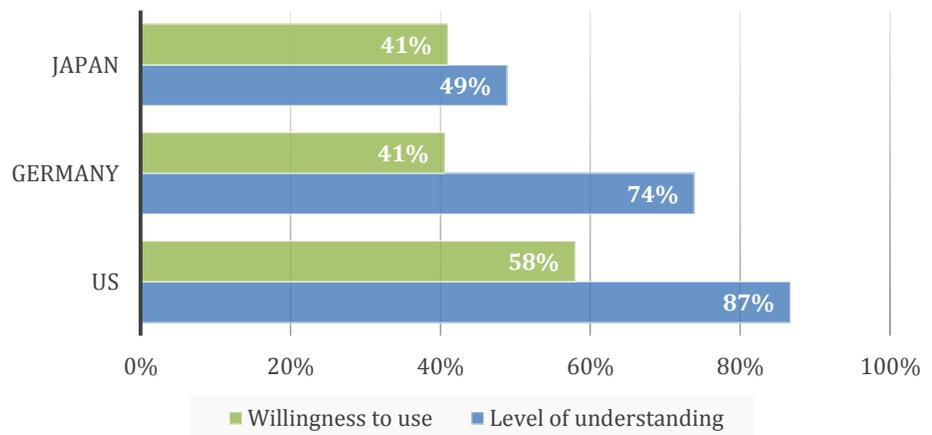
Source: Japan Ministry of Internal Affairs and Communications

Consumer concerns about data security when using wearable devices are generally high across the three markets. In a survey comparing consumers' concern in the US and Japan, more Japanese consumers appear to be worried about their personal data being breached (Exhibit 2).v

Exhibit 2: Consumer concern about data security in US and Japan

	Concerned	A little concerned	Indifferent	Not very concerned	Not concerned at all
US	47%	24%	17%	6%	5%
JAPAN	60%	23%	15%	2%	
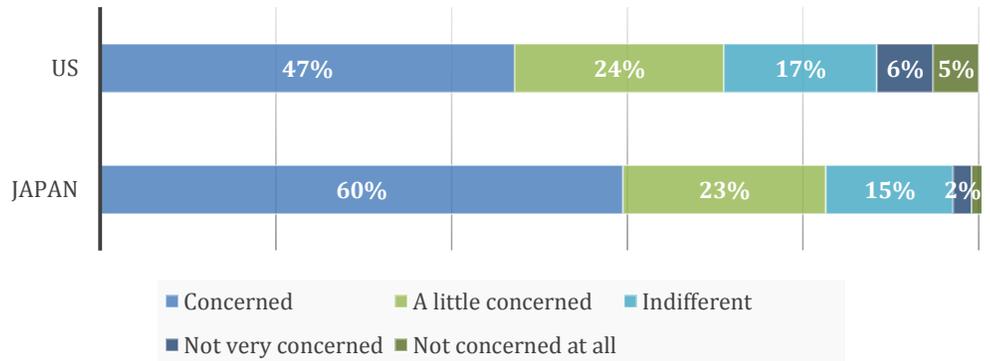
Source: Japan Ministry of Internal Affairs and Communications

US fitness wearable market 7x that of Germany and Japan

Revenue generated by the US, Japan and Germany fitness wearable markets combined is estimated to be $1.2 billion in 2017 and to reach $1.8 billion in 2020.

● The US market size is much larger in revenue and number of users (Exhibit 3 & 4).

Exhibit 3: Fitness wearable market size (revenue in million USD)

Year	US	Germany	Japan
2017	940	131	143
2018	1107	158	165
2019	1265	181	182
2020	1418	200	195
2021	1567	213	203

Source: Statista

Exhibit 4: Number of fitness wearable users (million)
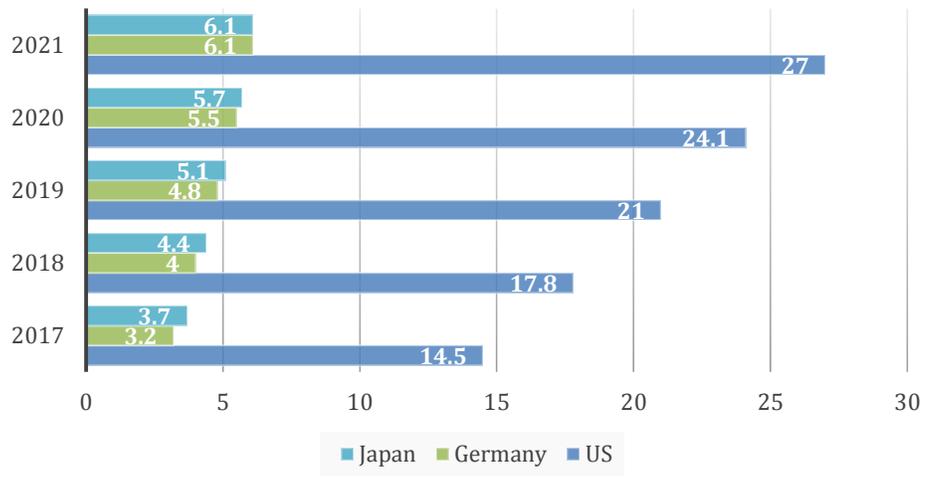
Source: Statista

- Revenue growth rates are projected to slow in all three markets, with the US market maintaining the highest growth (Exhibit 5).

Exhibit 5: Fitness wearable market revenue growth
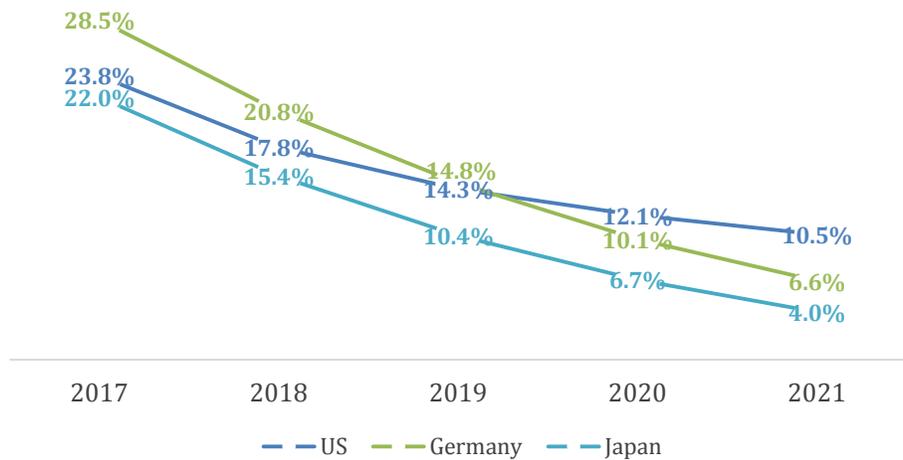
Source: Statista

- The US and German markets have higher user penetration with projections of hitting nearly 10% in five years. User penetration in Japan is lower with less expected growth (Exhibit 6).

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Exhibit 6: Market Penetration of fitness wearables

2017
- Japan: 3.4%
- US: 5.6%
- Germany: 4.6%

2021
- Japan: 5.7%
- US: 10.0%
- Germany: 9.0%

Legend: ■ Japan ■ US ■ Germany
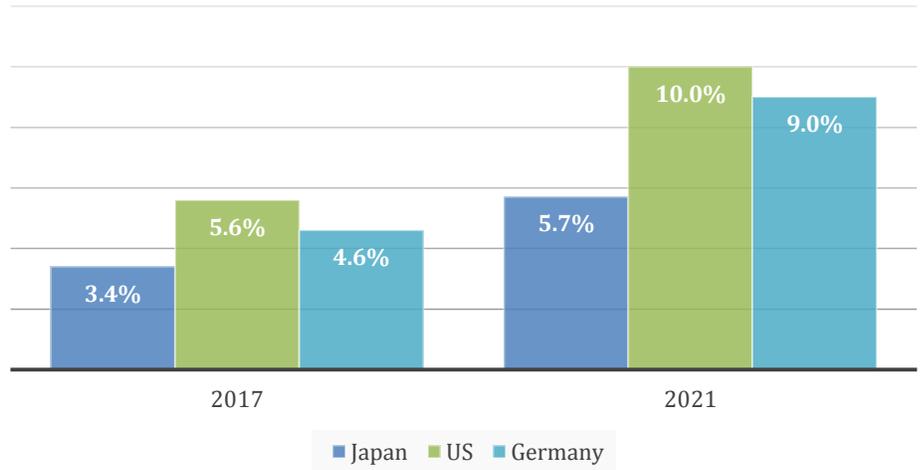
Source: Statista

mHealth wearables market will more than triple by 2019

According to BCG, healthcare and medical devices that allow remote consultations and targeted-care delivery projected global market size is estimated to increase from $62 billion in 2015 to $90 billion in 2020[vi].

Wearable devices in the healthcare and medical segment, also called mHealth wearables, will more than triple by 2019 with growth projected at nearly 30% per year, as a result of the aging population and an expected increase population with medical conditions (Exhibit 7)[vii].

Exhibit 7: Estimated Growth of Wearable Medical Devices Market, By End Use Applications

Years: 2014, 2015, 2016, 2017, 2018, 2019, 2020

Legend: ■ Home Health Care ■ Remote Patient Monitoring ■ Fitness and Sports
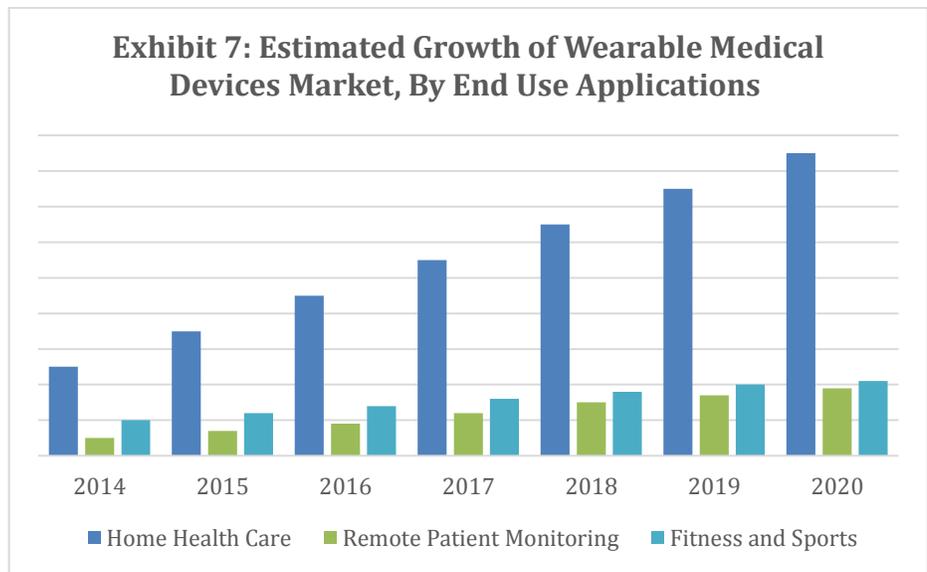
Source: Industry ARC Analysis, Expert Insights.

Remote-monitoring and clinical-grade wearables expanding

An aging population and increasing deaths caused by lifestyle-related diseases offer significant opportunities for wearable monitoring and clinical care devices. The aging population is a public health challenge in all three markets, especially Japan and Germany. By 2020, one in every four people in Japan and Germany will be over age 65 (Exhibit 8). There will be increasing demand for monitoring devices in the home and institutional care environment.

Exhibit 8: Aging population expansion (% of population)
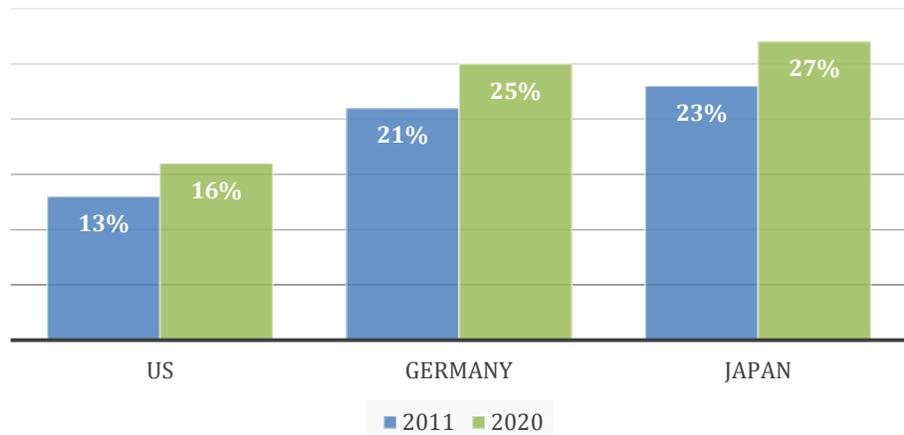
Source: Global Industry Analysts Inc.

The increasing aging population is also associated with increased treatment of chronic diseases: two-thirds of those over age 65 experience multiple chronic conditions. In the US, for instance, 95% of older Americans' healthcare costs are for managing their many chronic conditions, according to U.S. Centers for Disease Control and Prevention.[viii]

The prevalence of lifestyle-related non-communicable diseases (NCDs) is another common trait across three markets (Exhibit 9). NCDs are estimated to account for 88%, 91% and 79% of deaths in US, Germany and Japan respectively.[ix] Cardiovascular diseases, cancer and chronic respiratory diseases are the top 3 killers. These major NCDs are usually preventable and share common lifestyle-related risk factors like physical inactivity, unhealthy diet, tobacco use and harmful use of alcohol.[x]

Exhibit 9: NCDs proportional mortality
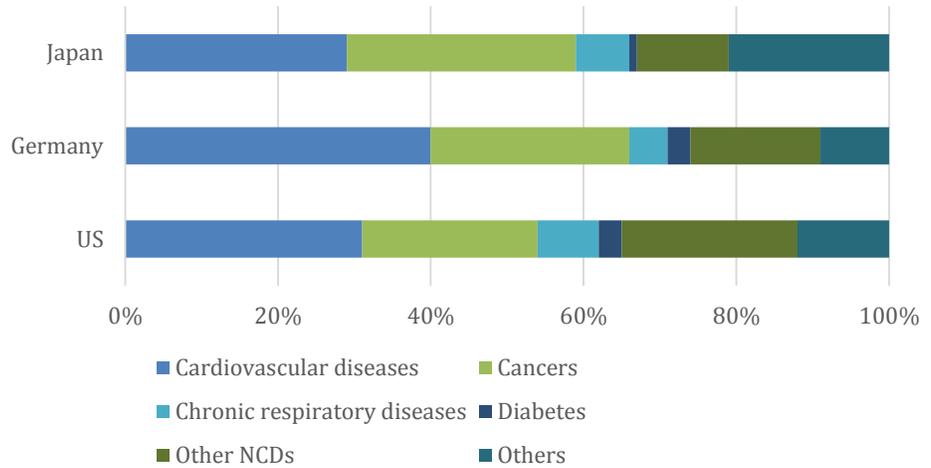
Source: World Health Organization

The prevalence of lifestyle-related NCDs presents abundant market opportunities for medical grade wearable devices. Frost & Sullivan's research shows that diabetes, multi-parameter vital monitoring system, cardiovascular diseases hypertension, sleep disorders and obesity account for over 70% of global healthcare spending. These areas have the largest potential market value of health wearables by 2020 but also have more market competition (Exhibit 10).

Exhibit 10:
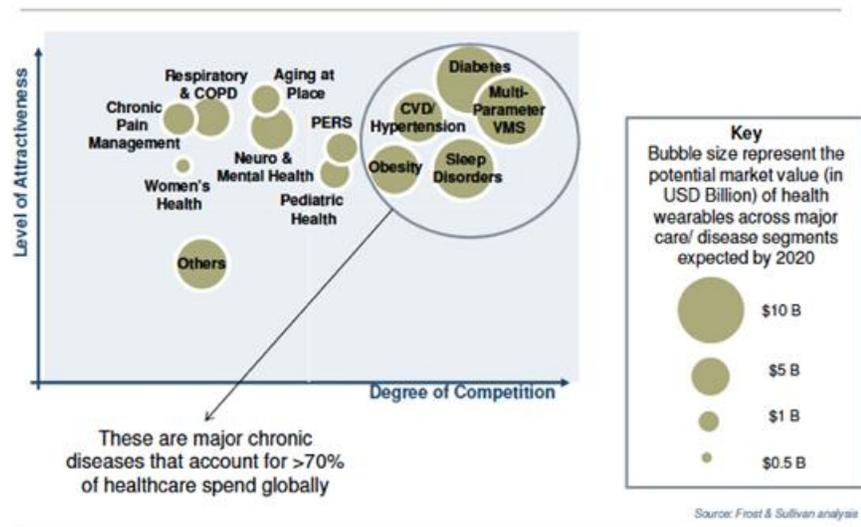
Source: Frost & Sullivan

Legal framework for medical devices regulation

Regulatory body

In the US, the Food and Drug Administration (FDA) is the only regulatory body that monitors medical devices. In Japan and in Germany, national government agencies PMDA and ZLG, respectively as well as nationally accredited institutions are involved in the premarket qualification process.

Scope of regulation

In all three countries, the definition of a medical device is based on the intended use of products. Devices that are intended for use in diagnosis, treatment, or prevention of diseases are regulated.

Classification of devices

All three countries have classification system of medical devices, although a particular product may not necessarily fall in the same category across three countries.

Premarket requirements

Premarket requirements varies depending on the class of a product as follows.

- In US, Class I devices are exempt from premarket procedures. For Class II and Class III devices, 510(k) clearance and approval by FDA are required respectively.

- In Japan, manufacturers must notify PMDA of marketing Class I devices. For Class II devices, certification by a registered body is required. Class III and Class IV devices requires approval by PMDA.

- In Germany, Class I devices can be marketed upon the manufacturer's self-declaration of conformity to quality standards. For Class II and Class III devices, conformity assessment by an official body is required.

Compatibility of premarket qualification

US and Japan require premarket qualification for products that are qualified as medical devices abroad. The EU has established quality standards applicable to all member states, so in Germany and in other EU member states, products with the CE mark can be marketed without additional qualifications no matter in which member state the manufacturer conducted conformity assessment for the CE mark.

Regulation on software

All three countries have established and developed laws and guidelines to appropriately regulate software in recent years. In US and Japan low-risk mobile applications or low-risk software are excluded from regulation. In the EU, upgraded risk-based classification is required of some software with tightened regulations.

Legal framework for health data privacy

The US does not have federal regulations for personal data protection applicable to all industries, while Japan and Germany have more comprehensive laws at the national level.

- The HIPAA Act in the US aims to protect patient healthcare information and covers entities such as healthcare providers, doctor's offices, health insurers and their business associates.

- Japan's Protection of Personal Information Act covers private entities regardless of industry. Businesses are also subject to guidelines established by government agencies for different industries.

- Germany's Federal Data Protection Act is applicable to private and public entities regardless of industry. Businesses in Germany must abide by the EU's General Data Protection Regulation as well.

Regulatory body

Japan has a national-level regulatory body, the Personal Information Protection Committee. Germany has the Federal Data Protection Commissioner as well as Data Protection Authorities in each state. In the US, the Office for Civil Rights in the Department of Health and Human Services (HHS) and Federal Trade Commission (FTC) are the major federal agencies involved in data protection.

Scope of protection

All these laws regulate handling of personally identifiable data. Therefore once data is anonymized, these laws do not require the data to be protected.

Scope of entities covered

Due to the limited coverage, HIPAA cannot be applied to wearable-related service providers unless data are handled by covered entities or their BAs. To fill the regulation gap, federal agencies have encouraged voluntary data protection efforts by businesses as well as expanding the definition of BA. In Japan and Germany, wearable-related service providers are subject to current laws.

Transfer of data

In all three countries, regulated entities need an individual's consent or authorization to transfer personal information to other entities in principle.

Right to access

Japanese law requires regulated entities to disclose or modify personal information upon request by an individual, but does grant individual rights to electronic copy of data. The EU's GDPR and the US's HIPAA grant individual rights to direct access of electronic health data. EU's GDPR is more complex because it requires healthcare providers to transfer and accept data in a commonly used electronic format.

US market
Opportunities for cognitive technologies
Increased adoption by athletes

Unlike the uncertainty with fitness wearable use among the general population, usage among amateur and professional athletes appears to be a strong market. A survey conducted in 2016 among over 700 amateur and professional athletes about wearable device preferences indicated wide usage among endurance athletes who expressed interest in data such as distance, pace, GPS and mapping, heart rate, time, and elevation.[xi] Only 1 out of 6 surveyed did not own a wearable device and a majority owned 2-3 devices.[xii]

Advanced fitness wearables combined with AI or machine-learning platforms offer the possibility of personal training. Devices in this category include the athletic coaching hearable developed by Boltt offered in partnership with fitness tracker powerhouse Garmin, Vi created by New York-Based LifeBEAM, garments by Sensoria, or Oakley's Intel collaboration for Radar Pace smart sunglasses.

Wearable devices are increasing in popularity among professional athletes and teams. The United States Olympic Team athletes turned to wearable devices for a competitive edge in preparation for the Rio Olympics.[xiii] For example, members of the diving team wore sensors indicating how high they jumped and how long it took them to get into their first spin.[xiv] Boxers benefited from the use of punch tracker Hykso, which provided key metrics such as time between attacks.[xv] The cycling team used Solos smart glasses to see real-time metrics without having to look down at a bike computer.[xvi] According to the Director of Technology and Innovation at the United States Olympic Committee Mounir Zok, "wearable technology" is still a very new term, but the devices taking the stage have already transformed the coach-athlete relationship from one driven by emotion to a healthier one based on evidence and data.[xvii]

Sports federations increasingly show a willingness to include wearable technology during competitions. Most notably, Major League Baseball has led the way in allowing wearable technology during practice, workouts, and now during competition. The league has approved a variety of bat sensors and swing trackers by analytics companies Blast Motion, Zepp Labs, and Diamond Kinetics for practice and workouts. In March 2017, the league announced players will be allowed to wear the WHOOP strap in games for the upcoming 2017 season. The company recently conducted the largest performance study in the history of professional sports, continuously monitoring 200 players and gathering enormous amounts of quantifiable data with practical applications on sleep, strain, and recovery.[xviii]

The National Basketball Association[xix] has begun to address the use of wearable technology by its players as well as the National Football League.[xx]

The next stop will be allowing wearable to enhance the sports fan experience at stadiums with data from athletes and games.

Cardiovascular disease market for home heart monitors

Chronic diseases are widespread, difficult to manage, and costly to the healthcare system. In particular, cardiovascular disease provides a substantial market:

- Cardiovascular disease ranks as the leading cause of death in the United States, accounting for 1 out of every 3 deaths for a total of 801,000 deaths a year.[xxi]

- About 92.1 million American adults are living with some form of cardiovascular disease or the after-effects of a stroke.[xxii]

- Each year about 790,000 people in the United States have heart attacks and 795,000 experience a stroke.[xxiii]

- About 47% of sudden cardiac deaths occur outside a hospital, suggesting that many people do not act on early warning signs.[xxiv]

- Direct and indirect costs of cardiovascular diseases and stroke are estimated to total more than $316 billion, including health care expenditures and lost productivity.[xxv]

- By 2030, health care costs for heart disease alone are estimated to rise to $1.1 trillion.[xxvi]

Businesses have responded to the prevalence of cardiovascular diseases by creating wearable devices, including those that pair with mobile phone technology to provide real-time, medical-grade electrocardiograms (ECGs) at home. When embedded in a wearable or mobile device and accompanied by smart algorithms, ECG biosensors can shed light on a variety of advanced biometrics such as heart rate, heart rate variability, stress, fatigue, heart age, breathing index, and mood.[xxvii]

Notable technology companies with home heart monitors include:

AliveCor won the first FDA approval in 2014l for a mobile heart monitor device to detect a serious heart condition.[xxviii] Consumers purchase the Kardia Mobile ($99) and also download the free mobile application Kardia. By resting the device on the fingers or the chest, the consumer can record a real-time ECG that gets transmitted through the mobile phone's microphone. Among other things, the user can "instantly know if atrial fibrillation (AF), the most common heart rhythm disturbance and a leading cause of stroke, is detected" in the ECG."[xxix] The device uses an artificial intelligence platform to help with detections and predictions.

Depending on the reading, the device sends various alerts: possible AF, normal, or unclassified i.e. if the device detects something else outside of AF including interference.[xxx] The ECG is stored in a cloud from which the consumer can print or send to their physician. Providers can also log into a free web-based application to review patient ECGs. Alternatively, the consumer can submit the ECG from the application and buy a technician-only analysis ($9) and a cardiologist review and recommendation ($19).

Newer consumer products promise truly continuous and long-term monitoring, which means more data points for collection and analysis. In January 2017, Qardio, Inc. announced its highly developed wearable [QardioCore](#) ($449) heart monitor device. Consumers use the wearable chest strap sensor weighing .29 pounds with a free mobile application. When the strap is worn and application is open, the strap automatically records an ECG and is capable of streaming 20 million data points to a smartphone a day.[xxxi] The device, available for pre-order and expected to ship April 2017 once the device obtains FDA clearance, will offer consumers the ability to automatically share the data with their physician.

Current state of market
Fitness wearables for general population face uncertainty
Since the arrival of Fitbit in 2009 and many others, fitness wearable devices still have a strong presence in the United States market despite smaller than predicted growth and competition from smartwatches. A December 2016 report from *eMarketer*, noted wearables like Apple Watch and Fitbit were expected to grow more than 60% year-over-year from 2015 to 2016. However, the firm later cut that estimate to just 25% growth for 2017.[xxxii] Fitness trackers still attract the younger demographic with low price points and a clear use case compared to smartwatches.[xxxiii]

Though fitness trackers dominate the wearable market, the rate of growth could slow. The firm *eMarketer* estimated the use of wearable devices would only reach 15.8% of the population in 2017, and is only expected to grow to 21.1% by 2020.[xxxiv] Moreover, while purchases of trackers will continue, the amount a person may use the device is uncertain. In 2015, a research firm found one-third of fitness trackers were abandoned within six months.[xxxv]

Fitness wearables: toward integrated devices
Emerging fitness wearable technology indicates wrist-worn devices such as *Fitbit* may be a thing of the past. Companies with newer wearable devices are beginning to integrate sensor technology into wearables such as shirts, shoes, pants, bras, and more. As technology becomes more advanced and integrated, there should be more data points, higher accuracy, aggregated data, and the incorporation of machine-learning capabilities.

Several major apparel brands have launched fitness apparel with sensors that pair with a smartphone including [Ralph Lauren](#) with its Polotech Shirt, [Under Armour's](#) smart shoe, and [Levi's](#) in collaboration with Google for its

connected Commuter Trucker Jacket. Newer wearable technology companies such as California-based Athos and California-based Lumo Bodytech have also make smart apparel.

A more advanced generation of fitness wearables are progressing beyond embedded sensors and toward making the device part of the fabric itself through the use of **conductive yarn.** According to Sabine Seymour, Assistant Professor of Fashion and Technology at the Parsons New School for Design in New York and founder of AI fashion wearable company SUPASPOT, these devices still face early challenges from the traditional textile industry and low margins that do not encourage risk-taking in technology.[xxxvi]

Market has not gained sufficient consumer trust for home monitoring devices

A recent survey by the Consumer Technology Association suggests consumers show willingness to share personal health data with their primary care physicians and primarily for the purpose of monitoring health or to track a medical condition.[xxxvii] However, 74% of respondents indicated they do not currently use a health monitoring device, which may be due to issues surrounding privacy and perceived benefits.[xxxviii] The *Deloitte 2016 Survey of US Healthcare Consumers* similarly found patients and caregivers have an appetite for technology-enabled care; but they demand high-quality, personalized care and want assurance that their personal information will be safe.[xxxix] Therefore, many device manufacturers focus on the needs for accuracy, reliability, and data protection. Once these devices gain trust and become mainstream, more data will be available to aggregate and analyze with machine-learning.

Smart patches and ingestibles in the hospital setting

According to a 2016 survey, 80% of hospital executives say predictive analytics could significantly improve healthcare.[xl] Recent developments in clinical wearable devices are providing continuous patient monitoring while collecting and analyzing important data. Such devices improve accuracy, reduce human errors, cut down on hospital staff costs, provide real-time updates to caregivers, and prevent adverse events.

Startup VitalConnect makes an advanced **sensor-embedded patch,** which tracks heart rate and temperature; takes single-lead ECGs; and provides relevant feedback to remote healthcare professionals. The company also focuses on applications for clinical trials, and it uses big data in its device to provide predictive analytics, a factor which interests hospital management.

Nearly 1 million patients fall every year in the United States, increasing hospital stays and healthcare costs, but predictive analytics and devices may soon improve the situation.[xli] Vocera **hands-free and voice-activated wearable** communication device is worn by doctors and nurses in over 1,400 organizations, and it integrates over 120 clinical systems, including electronic

health records, nurse call systems, physiological monitors, ventilators, and real-time location systems.[xlii] When combined with the predictive analytics capabilities of artificial intelligence software like [Qventus] Vocera has been able to notify nurses in real-time of patients in immediate risk of fall, cutting falls by 30% in one hospital.[xliii]

In 2016, digital medicine company [Proteus] announced the first commercial deployment to a health system for **ingestible device** Proteus Discover.[xliv] Among other things, the device helps patients with long-term chronic conditions adhere to medications. A patient's medications are co-encapsulated with a sensor that communicates with a patch worn on the body. The patch records the time of ingestion and personalized data such as heart rate, activity, and rest. This information is then relayed electronically to the patient through an application on a mobile device, which also provides support and insight to the patient and allows them to share their data with their healthcare professional. Physicians and their care teams can access a web-based physician dashboard where they are provided with objective data that can inform personalized treatment decisions.[xlv] Researchers at [MIT] have also developed similar ingestible technology.

Legal framework for medical device regulation
Intended use is a factor of the definition of medical device
In the US, medical devices are regulated by the FDA. The Food, Drug, Cosmetic Act (FD&C Act), established in 1938 and amended in 1976, provides basic regulatory framework for the regulation. In the FD&C Act, manufacturers' intended use of their product is a major factor of the definition of a medical device. If a manufacturer claims that its product is intended for use in the diagnosis treatment or prevention of disease, or is intended to affect human body, the product is subject to regulations on medical devices.

The FD&C Act classifies medical devices into three categories based on the risks to human body. It specifies premarket procedures necessary to provide reasonable assurance of safety and effectiveness for each category. Risk categories and premarket procedures are summarized as follows.

- Class I: Exempt from premarket procedures.[xlvi]

- Class II: Required to go through 510(k) notification. Marketable only after FDA clears the notification.[xlvii]

- Class III: Clinical trial and approval by FDA required.[xlviii]

General wellness wearables not FDA regulated
The FDA has published non-binding, but influential guidance applicable to wearable devices. In the FDA's latest guidance in 2016,[xlix] it clarifies that it does not intend to examine low risk "general wellness products" for regulatory purposes.

The guidance list two categories of general wellness products: 1) products of which the intended use relates to maintaining or encouraging a general state of health or a healthy activity without any reference to diseases or conditions; and 2) products of which the intended use relates the role of healthy lifestyle with reference to diseases or conditions[l]. According to the guidance, a product tracking "activity sleep patterns and promotes healthy sleep habits, which, as part of a healthy lifestyle, may help reduce the risk for developing type 2 diabetes" falls under the category of general wellness products, and thus is not regulated regardless of its reference to a disease.

FDA gives low-risk mobile applications some leeway

Given the rapid expansion and broad applicability of mobile applications, the FDA issued "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff" in 2015. In the Guidance, the FDA makes it clear that it does not intend to regulate mobile apps that may meet the definition of medical devices, but pose a lower risk to the public. For example, mobile apps that allow a user to collect blood pressure data and share the data to electronic health record is listed as an example of un-regulated mobile apps. On the other hand, examples of mobile apps that are the focus of regulatory oversight are also listed. Mobile apps that use a sensor to measure and display the electrical signal produced by the heart is included in the examples. [li]

Legal framework for health data privacy

HIPAA regulates organizations handling health information

HIPAA is the US statutory foundation to ensure the privacy and the security of a patient's health information. HIPAA provides legal requirements on a **covered entity,** which is any organization or corporation that directly handles patients' Protected Health Information (PHI) or Personal Health Records (PHR). Healthcare providers such as hospitals, doctors' offices, and health insurers are included in covered entities.

Covered entities must comply with the **Privacy Rule,** which covers a broad range of individual health information, as well as the **Security Rule,** which assures the availability, confidentiality, and integrity of electronic protected health information (e-PHI) through a series of administrative, physical and technical safeguards. Health-related data is protected only when it constitutes personally identifying data. For example, blood pressure data is not protected until it is linked to a patient's data.

In 2009, The Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted to stimulate the adoption of electronic health records (HER) and to support health information technology in the US. HITECH and HIPAA are two separate and unrelated laws, but they do reinforce each other.[lii] For example, technologies and technology standards promoted under HITECH should not compromise HIPAA's Privacy Rules and Security Rules.[liii] Also, several provisions strengthen the civil and criminal enforcement of the HIPAA rules.[liv]

Data collected via wearables may not be subject to HIPAA

Introduction of digital health products has raised concern about the coverage of HIPAA. Health information that patients input or record on social media or healthcare apps can hardly be protected by HIPAA, since the providers of these services are not covered entities. It is also pointed out that the issue could be complicated in the context of wearable devices where the device manufacturer, mobile app developer, and a HIPAA covered entity or business associate interact with each other.[lv]

For example, the data generated through a wearable device is not bound by HIPAA regulation since the device manufacture and the mobile app vendor are not covered entities. However, once the data is shared with a HIPAA covered entity like a hospital, the data held by the hospital will be protected.

Cloud service providers became subject to HIPAAA

In 2013, the Department of Health and Human Services published the Omnibus Rules, which is the final Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the HITECH. Before the Rules were issued, entities that use or disclose PHI on behalf of a covered entity were included in business associates (BAs).[lvi] Omnibus Rules significantly expanded the scope of BAs so that subcontractors who act on behalf of a BA is also responsible for PHI as a BA.[lvii]

If an entity "creates, receives, maintains, or transmits PHI"[lviii], it is a BA. For cloud service providers, "maintain" is most notable in the new rule. Once electronic protected health information (EPHI) sent from a covered entity is stored or "maintained" in the cloud, the cloud service provider becomes subject to HIPAA regulation as a BA.[lix]

FTC encourages voluntary codes of conduct

The Federal Trade Commission has taken a keen interest in protecting consumer-generated health big data. In 2015, the Health IT Policy Committee published recommendations on privacy and security challenges associated with big data. The major recommendations are as follows.

- The Committee encourages businesses to establish "voluntary codes of conduct" to achieve transparency, individual access, accountability and use limitation of big data.

- It encourages creating an individual's "rights to access" their health information maintained by entities that are not covered by HIPAA. [lx]

- It encourages public and private sector organizations to educate stakeholders about cybersecurity risks and recommended precaution,[lxi] including technology vendors.

Japanese Market
Opportunities for cognitive technologies
Rapid growth but data transfer may have legal barriers

In Japan, population aging and increasing lifestyle-related diseases will expand the opportunity for remote-monitoring devices and clinical-grade devices. An industry expert also confirms that remote medicine and home-based care are the key trends in Japanese healthcare. Watson could leverage the data collected through those devices to better assist physicians and users as well as to enhance research activities.

However, if a wearable device is designed to be used for diagnosis or treatment of a particular disease, the data collected through the device is often combined with the name of the disease. Individuals' history of diseases is subject to greater protection by law and transfer of such data, if not anonymized, is strictly limited. This would be the major constraint on opportunity for Watson.

Private health insurers may provide support

Lack of insurance coverage for fitness services be limiting the penetration of fitness wearable devices. The public health insurance scheme only covers diagnosis and treatment of diseases and injuries, and thus fitness services need to be paid for by individuals not by public funds.

Efforts by private health insurers may expand opportunity for fitness wearable devices. Some insurers have begun to encourage their customers to use fitness wearable devices. A recent case is Sompo Japan Nipponkoa Himawari Life Insurance Inc. The company distributed Fitbit to policyholders to collect data on health conditions. The company uses the data not only to set premiums, but also to identify causal relationships between diseases and particular lifestyle habits in order to develop new insurance products.[lxii]

Hitoe fabric has potential for wide range of applications

Hitoe is fabric developed by Toray Industries and Nippon Telegraph and Telephone. Hitoe applies an electro-conductive polymer to nanofibers, turning the resulting fabric into a collector of physiological electrical data. It can measure activities of heart, respiration, and muscles in unconscious fashion.[lxiii] The technology not only helps effective sports training but also has a wide range of opportunities for applications.[lxiv] The companies plan to introduce this technology to support home-monitoring and post-surgical monitoring.[lxv]

The companies are currently working with Fujita Health University to conduct a joint experiment to verify the effectiveness and potential of Hitoe for collecting quantitative medical data in the field of rehabilitation. After confirming the effectiveness of the Hitoe sensor, the companies plan to use it to implement rehabilitation services. They also plan to verify the smooth application of Hitoe within the RSH (Robotic Smart Home) project, which is

aimed at developing "smart homes for the elderly" that use life-support instruments and nurse robots.[lxvi]

Exmedio provides a doctor-to-doctor consultation platform

Exmedio is a startup that provides a remote medical diagnosis platform in dermatology and ophthalmology. Doctors who do not specialize in dermatology or ophthalmology use the platform to consult the specialists on clinical diagnosis and effectiveness of medicines by sending images of affected areas through mobile application.

Current state of market

Government aims to improve information infrastructure

The government aims to enhance the utilization of information and communication technologies and health-related data to improve the efficiency of healthcare and to ensure patient-centered decision-making. The recommendation by advisory panel of the Ministry of Health, Labor and Welfare (MHLW) includes the following improvements in healthcare information infrastructure.

- Develop infrastructure for remote medicine including diagnosis, treatment and surgery.

- Enable individuals to comprehend their health-related data and to manage their own health proactively by establishing information platform in which individuals have access to personal health data.

- Expand clinical database to enable healthcare providers to choose more effective treatment options and incentivizing such an effort by healthcare providers.

- Unify insurance-based payment database to be able to analyze performance of treatment options at national level.[lxvii]

Low understanding and willingness to use wearables

In general, the number of wearable devices in Japan is growing. According to the Ministry of Internal Affairs and Communications, there were 2.09 million units of wearables in 2015 and the number is estimated to increase to 11.6 million in 2020.[lxviii]

However, Japan has a lower level of understanding of wearable devices and willingness to use them compared to other countries. Surveys found 70-80% of people from the US, UK, Germany, Australia, India, Korea, and China have some level of understanding of wearable devices while the percentage for Japan is only 48.9%. There is also a higher percentage of users indicating concerns about wearable devices. Over 80% of people surveyed expressed their concerns that their sensitive data collected through wearable devices might be more easily obtained or misused by a third party (Exhibit 11).[lxix]

Exhibit 11: Japanese people have greater privacy concerns towards wearables

US	47.2%	23.8%	17.4%	6.4% 5.2%
JAPAN	59.5%	23.1%	14.5%	2.1% 1.8%

Legend:
- Concerned
- A little concerned
- Indifferent
- Not very concerned
- Not concerned at all
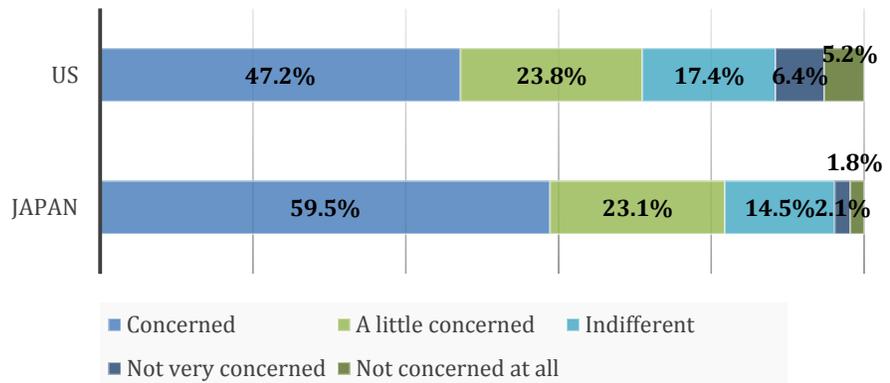
Source: Ministry of Internal Affairs and Communications

Low penetration partly due to lack of insurance coverage

In Japan, the mobile fitness market amounts to US$235 million in 2017, and is expected to show annual growth of 11.1%, resulting in market volume of US$358 million in 2021. The wearable segment in this market is estimated to account for US$143 million in 2017. Market penetration of fitness wearables and applications are lower than in other markets such as the US and major country in EU (Exhibit 12 and 13). This indicates that compared to other countries, consumers in Japan tend not to use wearables for fitness purposes.

Exhibit 12: Market penetration of fitness wearable devices is low in Japan

Country	2017	2021
JAPAN	3.4%	5.7%
US	5.6%	10.0%
GERMANY	4.6%	9.0%
FRANCE	4.6%	9.5%
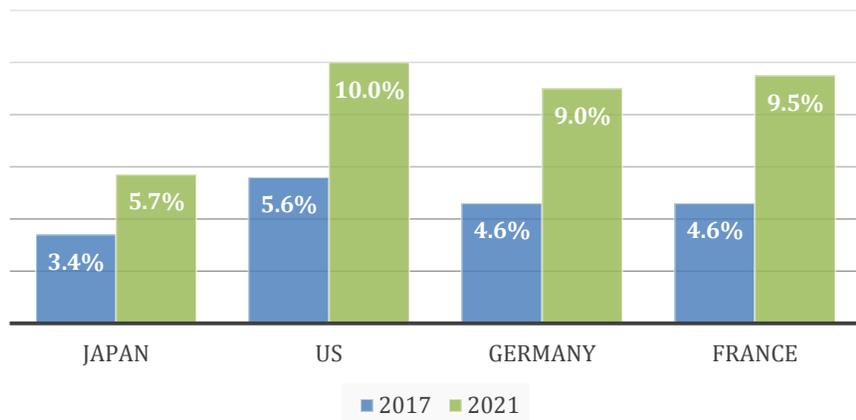
Exhibit 13: Market penetration of fitness applications

Bar chart showing market penetration of fitness applications for 2017 and 2020:
- JAPAN: 6.5% (2017), 10.4% (2020)
- US: 10.0% (2017), 14.8% (2020)
- GERMANY: 9.6% (2017), 16.1% (2020)
- FRANCE: 8.3% (2017), 15.7% (2020)

Source: Statista

Lack of insurance coverage might be one of the factors that have limited the use of wearable devices for fitness purposes. The public health insurance of the country only covers diagnosis and treatment of diseases and injuries. Preventive measures including fitness services are not eligible for insurance reimbursement.[lxx] As a result, users of fitness services have to pay the full cost of the service while providers of fitness services tend to suffer from lack of stable revenue sources. An industry expert confirms this view by stating that from business perspective, services that are covered by public health insurance are more attractive in terms of profitability.

Rapid growth from aging and home-based care needs

The rapid population aging is expected to increase the needs for care; 25% of the population is aged 65 or over. The percentage of elderly will reach 30% in 2033. The increase persists, reaching 35.7% in 2050; that is, 1 in 2.8 persons will be over 65.[lxxi] A report projects a shortage of 1 million caregivers by 2025 for Japan.[lxxii]

Healthcare for the elderly is shifting to home-based care from facility-based care. Some 38% of elderly wish to receive care at their own or a relative's home rather than in hospitals or nursing homes.[lxxiii] To ensure dignity and self-reliance, the government has promoted home-based care as an alternative to hospital and facility-based care.[lxxiv] The number of people who need home-based care is estimated to be 7.5 million by 2025.[lxxv]

Remote-monitoring devices will become essential to meet the increasing care needs and to ensure the effectiveness of home-based care. According to a report, the market of ICT-based home healthcare is expected to double from JPY 11.8 billion (about USD 103 million) in 2012 to 26 billion (USD 227 million) in 2020.[lxxvi]

Increased wearable use for chronic disease treatment

Wearable devices are being developed, tested and employed to treat chronic diseases. For instance, several medical device makers are selling personal portable heart activity monitors as medical devices. Kyoto University is conducting clinical trials on a device that routinely measures the heart rate of epileptic patients. If the device detects signs of a stroke, it notifies the patient via smartphones.[lxxvii] Sustainable Medicine, Inc expects to have its mobile application for insomnia treatment approved by 2020. Patients enter their sleeping time, daytime activities and concerns into the application. The application analyzes the information using an algorithm and suggests improvements.

The prevalence of lifestyle-related diseases and the medical expenditure associated with them are increasing. Lifestyle-related diseases account for 60% of all death and over 30% of total medical expense.[lxxviii] According to the data available from nine OECD countries, Japan spends the most on cardiovascular disease (CVD) and diabetes in hospital settings; USD 202 per capita for CVD and USD 23 per capita for diabetes.[lxxix]

Wearable devices can play an important role in improving the diagnosis and treatment of increasingly widespread lifestyle-related diseases. Daisuke Ichikawa, medical doctor and researcher of Sustainable Medicine, Inc, emphasizes the advantage of wearable devices in treatment of chronic diseases: they enable physicians to obtain their patients' data in a continuous and comprehensible manner, which is of great value for treatment of diseases that requires continuous effort to change the patients' habitual practice.

Legal framework for medical device regulation

Pharmaceutical and Medical Device Act regulates products

The Pharmaceutical and Medical Device Act regulates the quality, efficiency and safety of medical devices. The Pharmaceutical and Medical Devices Agency (PMDA) is the regulatory agency that conducts premarketing scientific review and monitors postmarketing safety. The intended use is the major factor to determine whether a device is subject to regulation as medical device[lxxx] as in US.

Streamlined premarket procedures on risk-classification

Medical devices are classified into four categories based on the risk to the human body. Each class is subject to different premarket procedures as follows.

- Class I: Marketing notification to PMDA required, but certification or approval not required.

- Class II: Required to comply with certification standards. Certification by a registered certification body required.

- Class III & Class IV: Scientific review by PMDA and approval by MHLW required.[lxxxi]

Scientific review and approval procedure may take six months to more than a year. [lxxxii] The government has made effort to mitigate this burden on medical device manufacturers while ensuring safety and quality. The certification procedure by registered certification bodies is aimed to streamline the premarket procedure for Class II devices. The Act was amended in 2013 to expand the scope of the certification procedure. The amendment allowed some categories of Class III and Class IV devices to be marketed without scientific review and approval.[lxxxiii] As for high-risk devices that still requires approval process, the government is committed to expanding the capability of PMDA to review applications for approval.[lxxxiv]

Some software subject to regulation

Software used to be regulated as a medical device only when combined with a medical device in form of hardware. However, in 2014 the government started to regulate software itself as medical device without being installed in computers or mobile phones. If software is intended for use in the diagnosis, treatment or prevention of diseases, it is now subject the regulation.[lxxxv] According to an industry expert, although more and more startups are interested in having their software products approved as medical devices, the complex procedures poses challenges to many.

MHLW has announced that will not regulate software that involves low risk to human bodies even if it is relevant to diagnosis, treatment or prevention of diseases. The followings are examples of software excluded from the scope of regulation.[lxxxvi]

- Software that censors body motions through mobile devices.

- Software that controls home environment electronics in response to health-related information sent through mobile devices.

- Software that provides recommendations and advice to promote general health and wellness in response to health-related information sent through mobile devices.

- Software that displays, transfer or store health-related measurements such as body weight, blood pressure and blood-sugar level for the purpose of daily general health management.

- Software that shares individual health records with general health service providers for the purpose of recording but not for diagnosis.

- Software that displays or stores medication history.

Legal framework for health data privacy
Personal Information is protected

Act on the Protection of Personal Information regulates the acquisition, retention and transfer of personal information. The Act provides legal obligations for all private entities including non-profit organizations that deal with personal information. [lxxxvii]

It also authorizes Personal Information Protection Committee (PIPC) and other government agencies to establish guidelines for different industries and to control violations. One of the major guidelines relevant to health-related data is the Guideline for Appropriate Handling of Personal Information by Healthcare Providers and Long-term Care Providers.[lxxxviii] The Guideline provides specific standards and examples of the way healthcare and long-term care providers should handle personal information including medical record and prescription. Health-related data may be also subject to other guidelines depending on the industries and the circumstances in which the data is handled.[lxxxix]

Businesses must specify intended use of information

In the Act, personal information to be protected is defined as information about a living individual which can identify the specific individual by name, date of birth or other description contained in such information.[xc] Upon the acquisition of such information, private entities are required to specify the purpose of utilization of personal information. They should promptly notify the individual or publicly announce the purpose they specified. They are allowed to handle personal information within the scope of the purpose.[xci]

Once personal information is organized into a database so that personal information of a specific individual can be retrieved by a computer, private entities have a greater legal obligation. They must ensure data security through appropriate security measures, supervision of employees, and monitoring of trustees.[xcii] Any leakage of personal data may be subject to government orders by PIPC or other government agencies as well as a claim for compensatory damages.[xciii] In addition, if a private entity is to retain certain personal data for more than six months, it is required to disclose, correct or delete personal data upon the request by any individuals included in the data. [xciv]

Data transfer to third parties requires prior consent

Private entities are not allowed to transfer personal data to a third party without obtaining the prior consent of the individual in principle. However, transfer of personal data does not necessarily require written consent. In some circumstances, private entities may infer implicit consent on the transfer to a third party. For example, a healthcare provider may notify the patient of the purposes of utilization, such as to cooperate with or seek opinions from other healthcare providers for the sake of provision of appropriate healthcare services to the patient. If a patient does not explicitly oppose the policy, the healthcare provider may infer the patient's implicit consent on the transfer of his data to other healthcare providers within the scope of the purpose.[xcv]

Private entities can transfer personal data to a group of private entities that jointly operate a business without prior consent. A private entity may notify individuals of specific items to be shared, specific businesses to share the personal data with and the purpose of sharing in advance. By doing so, the

business may share the personal information within the scope without prior consent for each transfer.[xcvi]

Private entities may also rely on opt-out procedure that allows them to transfer personal data to a third party without prior consent. In order to comply with the procedure, private entities are required to notify individuals in advance that the purpose of utilization includes transfer of the data to a third party. They also should specify the items to be transferred and the method of transfer. In addition, they must report to PIPC in advance, and PIPC will publicly announce the private entities that reported for opt-out procedure. If an individual requests to suspend transferring his or her personal data, the private entity must follow the request.[xcvii]

Sensitive personal information has greater protection

Personal information that may cause prejudice or discrimination against an individual is categorized as sensitive personal information in the Act that is subject to greater protection. Items such as race and history of diseases are included in sensitive personal information. While the fact that a person had a certain disease is included in sensitive information, information from which diseases might be inferred is not. For example, information on general health such as blood pressure and abdominal girth, results of blood test and x-ray image are not sensitive information.

Private entities are not allowed to rely on opt-out procedures for the transfer of personal data that includes sensitive personal information. Therefore, private entities are required to obtain prior consent without exception to transfer such data to a third party. In addition, private entities are required to obtain consent on the acquisition of sensitive personal information. These obligations provide greater protection of personal data including race and medical history.[xcviii] These obligations on sensitive information would be the major constraint on transfer and utilization of health-related data, according to an industry expert.

Businesses are responsible for anonymization

Once personal information is appropriately anonymized, private entities are allowed to handle the data outside the scope of the purpose of utilization. Anonymization also allows private entities to transfer the data to a third party without prior consent. In health care settings, for example, anonymized data from clinical trial can be shared among pharmaceutical companies, hospitals and research institutions, which is expected to enhance drug development.

There are two criteria for anonymization of data. Personal information must be arranged to prevent the identification of specific individuals. And., personal information cannot be restored to the original state that enables identification of specific individuals once it is anonymized. Deleting items that may lead to identification, such as name, data of birth, address, driver's license numbers, and finger prints is one of the most significant steps of anonymization. Any ID numbers that can be easily used to identify specific individuals may not be used for anonymization.

Private entities that anonymize personal information are required to take data security measures to prevent leakage of information that may help to restore the original data. Once they anonymize data, they are not allowed to collate the anonymized data with any information to restore original data. Upon transfer of anonymized data to a third party, they are required to publicly announce the items included and method of transfer.[xcix]

Amendments to the Act bring uncertainty

An amendment to the Act takes effect in May 2017 and includes the establishment of PIPC, expanded requirements for opt-out procedures for transfer to a third party without prior consent, greater protection for sensitive personal information, clarification of criteria for data anonymization, and requirements for private entities that anonymize data.[c] Those changes will greatly influence healthcare industries. However, there remains some ambiguity as to how strictly the new authority will enforce the Act and how businesses may react to it.

German market
Opportunities for cognitive technologies
Clue uses machine learning to predict menstrual cycle

Clue is a Berlin-based startup that has developed the menstrual cycle tracking application Clue App. The app is designed to track women's fertility accurately, and is fast and user-friendly. The app applies machine learning technology to predict women's periods, fertile windows, and premenstrual syndrome. The Clue app can be connected with Apple Watch and Fitbit HR.[ci]

Clue has a large, rapidly growing user base. Over 5 million women globally were actively using the Clue app as of February 2017. The US is Clue's biggest single market, a followe by Europe .[cii] Clue plans to achieve a more diverse age group of users. Clue has raised US $20 million in 2016, which brings its total financing to US $30 million since its launch in 2013[ciii]. The new funds will be invested in ongoing product and technology development.[civ] To guide its product development, Clue has partnered with several research institutions, including Columbia University, and appointed medical specialists from UCLA and Stanford University.[cv]

The large user base has enabled the company to accumulate data. It has been taking advantage of the large dataset to enhance its machine learning technologies.[cvi] Clue is building algorithms and is beta testing predictions based on body symptoms. The company engaged data scientists in March 2017 to create a smarter prediction model in terms of body symptoms without privacy issues. [cvii]

Femisphere creates outreach on value-based data analysis

Femisphere is a female healthcare and medical application created by the German-based healthcare technology company OneLife Health.[cviii] The app presents an mHealth solution for expectant mothers and doctors as a Class I

medical product. Female users who are pregnant or planning to get pregnant can track their vital data and symptoms as well as receive real-time feedback through a contextual algorithm. Users can share the data with medical professionals and digitally connect with them between doctor visits if necessary. The data shared can be easily integrated with software infrastructure, so that doctors can proactively access the data and test results and offer their patients in-time advice or schedule appointments[cix].

OneLife Health formed a partnership with Philips in February 2017. They will initially focus on further developing the app. As part of the agreement, Philips has acquired a minority interest in Onelife Health. According to an announcement, by leveraging the synergies between Philips' baby monitoring apps and Femisphere, both companies are expecting to improve and expand usage.[cx]

Current state of market

mHealth is driven by fitness- and health-conscious devices

Germany's health technology market mainly consists of small and medium-sized enterprises (SMEs). According to Germany Trade and Invest (GTAI), 95% of Germany's healthcare and medical technology companies have less than 250 employees.[cxi] The dynamic industry climate for SMEs provides a strong foundation for the success of the mHealth sector in Germany: start-ups become the main driver of the industry and new business models are constantly developed.[cxii]

According to ATKearney, revenue for Germany's mHealth sector, which includes wearable devices, apps and medical devices used for fitness, disease monitor and treatment, is projected to be €3.2 billion in 2017, growing at 22% annually. The largest mHealth segment is hardware, which will generate about €427 million with 33% projected annual growth.[cxiii] The hardware segment is still the largest, driven by fitness- and health conscious-devices.[cxiv] Germany has mobile penetration greater than 100%, which also provides a strong infrastructure for scaling up the mHealth market.

Those over 65 could become largest mHealth consumers

Germany's over-65 population will increase to 24 million in 2023 – a 7 million increase from the current 17 million.[cxv] As a result, the cohort is expected to account for one-third of the German population. At present, 50% of people over age 50 consume goods and services paid out-of-pocket. Those 50-plus have become the core target group in the out-of-pocket market, due to an aging population that expects a healthier and more self-reliant life.[cxvi] Those age 20 to 45 are still the main consumers in the mHealth market. If hardware vendors and technology innovators are able to introduce the benefits of mHealth to elders, they could become key consumers in the mHealth market.[cxvii] According to of PwC & GSMA, the demand for of mHealth, in particular, monitoring services, is booming, and independent aging devices are estimated to be 45% of revenues [cxviii].

Caution on wearables costing more than €300

The German out-of-pocket healthcare market has been growing at an annual rate of 4% for the last decade, and the average individual annual expenditure on out-of-pocket healthcare goods and services is €900.[cxix] However, pricing is still the key concern when consumers purchase wearables. According to a PwC study, about 71% of respondents said they wouldn't spend more than €100 ($133) on a wearable device. And 26.8% said pricing between €100 and €300 ($398) might be acceptable. Only 2% said they might be willing to spend more than €300[cxx].

Growth will slow upon market saturation

Fitness monitoring is driving the growth of the mobile health wellness segment, accounting for 80% of revenue in 2017.[cxxi] The fitness wearable market is estimated at $131 million in 2017 and $213 million for 2021, with estimated annual growth of 12.9%. The growth of fitness wearables could further enhance people's confidence in controlling their medical data.[cxxii] However, the market saturation will slow down the growth: the annual growth rate is expected to fall from 28.5% in 2017 to 6.6% in 2021.[cxxiii]

Compared to the US (5.6%) and   European countries such as the UK (5.5%) and Denmark (5.7%), German market penetration is relatively low at 4.6%. Although 74% of have some understanding of fitness wearables, the proportion of Germans willing to use wearables is a low 41%.[cxxiv]

A reason for this low penetration may be the lack of comprehensive reimbursement. Fitness wearables costs are not included in current health insurance system. As a result, consumers have to pay for wearables out of pocket.[cxxv] According to a 2015 PwC survey , 79% of Germans named "value of money" as the primary concern when considering buying a fitness wearable (Exhibit 14).[cxxvi] Without significant expansion in insurance coverage, the German fitness wearable market may stagnate to include only early adopters.

Exhibit 14:

Important factors when purchasing a wearable device according to internet users in Germany in February 2015
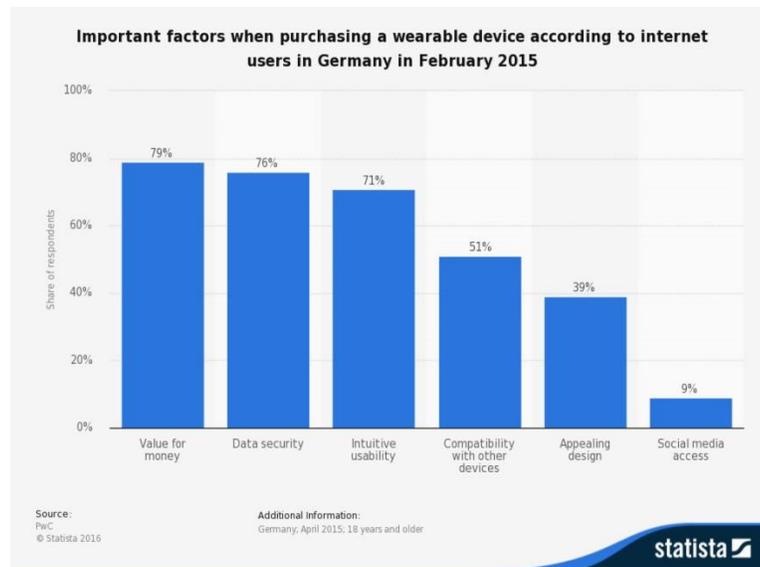
Source: PwC, 2015.

Remote monitoring has strong potential amid obstacles
A high prevalence of chronic diseases creates potential for remote monitoring wearables. In Germany, the highest percentage of deaths is due to non-communicable (chronic) diseases.[cxxvii] A study shows that remote monitoring of patients suffering from chronic diseases has become the primary and the most profitable application of mHealth.[cxxviii]

The market performance of remote patient monitoring for each chronic disease depends on the prevalence of the disease. Cardiovascular disease is the most frequent cause of death in Germany, accounting for 39.7% of all deaths, followed by cancer and metabolic disease.[cxxix] Monitoring solutions (including remote monitoring wearables) for cardiovascular disease in 2017 will generate 54% of chronic disease management revenues.[cxxx] Monitoring solutions for metabolic diseases are projected to comprise nearly 23% of the revenue.[cxxxi]

In spite of this strong growth potential, the market is more mature in many aspects. For example, clinical use of data collected through remote-monitoring wearables is facing obstacles. Health professionals are skeptical about the accuracy of data since it has not been proven.[cxxxii] Although qualification as a medical device can assure the validity of data, the process tends to be time consuming and expensive.[cxxxiii]

Legal framework for medical device regulation
EU oversight with member state implementation
The European Union (EU) has established a Medical Device Regulation (MDR), which includes essential requirements for the safety and effectiveness of medical devices that apply to all member states. Under the MDR, a medical device is defined based on the intended use of a device as

in US and in Japan. A class system differentiates four risk classes, from Class I, IIa, IIb and III.

The EU does not enforce the requirements. Each member state has a National Competent Authority and Notified Bodies that interact with manufacturers planning to market medical devices.[cxxxiv] The Medical Device Act stipulates the essential requirements for Germany. ZLG (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln Und Medizinprodukten) is the federal authority for medicine and medical devices that accredits Notified Bodies. Notified Bodies is in charge of conducting tests and issuing certificates in connection with conformity assessment procedures.[cxxxv]

CE mark required for the EU market

Medical devices must pass the conformity assessment procedures to obtain a CE mark.[cxxxvi] Since the CE mark is acknowledged in all member states, products with a CE mark do not have to go through additional assessment procedures in other member states.[cxxxvii] Manufacturers can put their medical devices with a CE mark out on any member state's market by submitting the summary of product characteristics in the respective member states' language to appropriate national authority. The general timeline for this process is three to nine months.[cxxxviii]

The requirements for the conformity assessment varies across the classes as follows.

- Class I: Must pass the conformity assessment conducted by the manufacturers and self-declare the conformity required.[cxxxix]

- Class II and Class III: Declaration of conformity needs to be supported by the conformity assessments from Notified Bodies.[cxl]

EU tightens medical device rules on software

Under the EU MDR, software is classified based on intended function and risks.[cxli] In 2016, the EU changed the classification of software. The change will cause up-classification issues for some software products, and therefore have significant influence on clinical decision support or physiological monitoring software. Following are the major changes in the software classifications.

- If the purpose of the software is to provide information that could help make decisions related to diagnosis or therapy, then it is in Class IIa or higher. The software will be Class IIb if the decisions could cause "a serious deterioration of the state of health or a surgical intervention." If the decisions could lead to death or irreversible deterioration of health of a user, the software will be Class III.[cxlii]

- Software will be Class IIa if its purpose is to monitor physiological processes. If software is designed to monitor "vital physiological parameters, where the nature of the variation could result in immediate

danger to the patient," it is Class IIb.[cxliii]

- All other software will be Class I.[cxliv]

Legal framework for health data privacy
Healthcare and telecommunication regulations complex

The key features of the Germany's Federal Data Protection Act are:

- Organizations must obtain explicit permission from an individual before collecting any personally identifiable information.[cxlv]

- Personal identifiable information includes "an individual's name, date of birth, phone number, address, and computer IP address."[cxlvi]

- The permission must be specific in terms of method, location, duration and purpose of retaining the information.[cxlvii]

- Individuals have the right to stop their data from being collected at any time.[cxlviii]

- Policies, procedures, and controls must be established by organizations to protect all data types covered by the Act.[cxlix]

The German Data Protection Authorities (DPAs) clarified through their resolution some applications of the Federal Data Protection Act in wearables and apps.[cl] Some of its provisions include:

- Manufacturers of wearables and healthcare apps should comply with the principles of data reduction, data minimization, anonymization and pseudonymization through using data privacy protection technologies as default settings.[cli]

- Manufacturers must obtain an individual's detailed consent regarding the collection, processing, and use of personal health data, particularly when their data will be transferred to third parties.[clii]

- Employers and insurers may obtain consent from employees and policy holders regarding the use of personal health data, but the consent is likely to be considered as invalid due to significant negotiating imbalances between the parties.[cliii].

- Individuals and organizations cannot waive legal requirements of data security through contracts or consent.[cliv]

- If multiple parties participated in the development or sales of wearables and healthcare apps, those parties have a joint responsibility for quality standards, IT security, functionality, and the transparency of data usage, but the operation of the joint responsibility is not explained clearly in the resolution.[clv]

In addition, the German criminal code and data protection laws at state level also provide regulations on data privacy for the healthcare industry.[clvi]

Invalidation of EU Safe Harbor complicates legal issues

The European Court of Justice (CJEU) invalidated the Safe Harbor in 2015. The Safe Harbor once allowed international businesses like Google and Apple to legally transfer their European users' personal data to the United States as long as they claim that they have met the requirements. Now, these businesses have to take other approaches to minimize compliance and enforcement risks, such as establishing contracts under the Binding Corporate Rules.[clvii]

Data Privacy legislation emphasizes consent & access

In 2016, the EU established the General Data Protection Regulation (GDPR). The GDPR aims to protect personal data as well as to ensure free movement of personal data within the EU. Healthcare data is treated as personal data, and therefore security and privacy protection need to be provided.[clviii]

GDPR requires that individuals are well-informed before their data are collected and processed. Individuals also have the access to their personal data. On the other hand, data controllers should be able to keep data in a secure system.[clix]

The "free movement of data" principle in the GDPR also has a significant impact on healthcare providers. Each patient has the right to move their personal data to a different healthcare provider in a commonly used electronic format. Therefore, healthcare providers must be able to identify and retrieve the personal health information of each patient and to transfer in a suitable format. A healthcare provider also must have the capacity to accept electronic data from another healthcare provider.[clx]

GDPR applies not only to all EU member states, but also to organizations outside the EU if the personal data concerned relates to EU citizens. Therefore, healthcare providers need to make sure that the cloud services that they are using could make them comply with GDPR.[clxi]

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