

## Big Health Data, Big Health Opportunities

How digitisation of the health sector can lead to a sustainable healthcare system and new business opportunities in ageing societies – a cross-country perspective from Japan and Germany

Written By

Professor Dr. Erwin Böttinger Professor for Digital Health, Personalized Medicine & Head of Digital Health Center Hasso-Plattner-Institute, University of Potsdam

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### Executive summary

In the last 60 years the proportion of the world population aged 65 and above has almost doubled from 5 percent to 9 percent.<sup>1</sup> Japan rates as prime example of a so-called 'super-aged' society. The elderly population (aged  $\geq$ 65 years) currently accounts for more than 27 percent<sup>1</sup> of the total population and is expected to exceed 30 percent in 2025.<sup>2</sup> Concurrently, birth rates have dropped considerably within the last 50 years.<sup>3</sup> Other western countries are characterised by similar demographic transitions. An ageing society poses a tremendous challenge to current healthcare systems. Akin to Japan, Germany is well on its way to becoming another 'super-aged' society and its healthcare system faces similar challenges.

Parallel to the demographic transition, our society is subject to a profound technological transition. This is linked to a continuous increase in electronic data, as ever new technologies are employed, which can collect, store and share it. A lot of the accumulated data contains relevant information about a person's health.

If we want to make sure that the burgeoning elderly population can live and age with dignity and a good quality of life, it is imperative that conventional healthcare systems adapt to these novel challenges. Healthcare digitisation is the key to sustainability. Establishing a high-level strategic approach and centralised coordination is necessary for success; however, concerns regarding data security and privacy of sensitive information are a key obstacle which often delay implementation of data-driven healthcare solutions.

Facing similar challenges in its population, Japan is creating a new regulatory framework for a next-generation healthcare system, where medical data and technology will be more usable for research institutions and private-sector businesses as well, for the sake of heath care innovation, advanced research and development, and new business creation. The fastest ageing nation in the world may be sharing 'ageing experiment' and new healthcare business opportunities with otherwestern countries; its approach to make data more usable will make it a highly attractive market for foreign direct investments and business partnership, along with the huge amount of quality medical data, tech-friendly citizens, and well-developed IT infrastructure for the healthcare sector. Japan can be an ideal test bed in an ageing society for foreign businesses.

Sharing issues of an ageing society, German businesses and organisations should leverage opportunities Japan is opening, for creating new solutions together.

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### Introduction

#### Challenges of an ageing society

In the last 60 years the proportion of the world population aged 65 and above has almost doubled from 5 percent to 9 percent.<sup>1</sup> This trend is even more pronounced in western countries, mainly due to their high-quality healthcare systems, access to advanced medical technologies and low birth rates. Japan rates as prime example of a so-called 'super-aged' society. The elderly population (aged  $\geq$ 65 years) currently accounts for more than 27 percent<sup>1</sup> of the total population and is expected to exceed 30 percent in 2025.<sup>2</sup> Concurrently, birth rates have dropped considerably within the last 50 years.<sup>3</sup> Other western countries are characterised by similar demographic transitions. An ageing society poses a tremendous challenge to current healthcare systems. It not only brings about changes in epidemiology and medical care demands (e.g. a higher incidence and prevalence of age-related and often chronic diseases) but will further boost healthcare expenditures. If we want to make sure that the burgeoning elderly population can live and age with dignity and a good quality of life, it is imperative that conventional healthcare systems adapt to these novel challenges.

#### Healthcare digitisation as key to sustainability

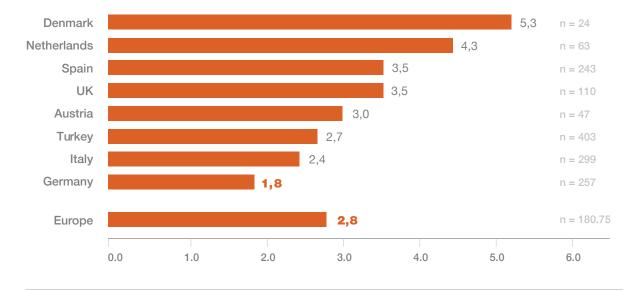
Parallel to the demographic transition, our society is subject to a profound technological transition. The internet has become a central part of our daily life, even in the age group above 65. While in the early 1990s only one in a hundred citizens had a mobile phone subscription in Germany, today it is on average more than one subscription per every person.<sup>4</sup> Currently more than 60 million Germans use a smartphone.<sup>5</sup> This is linked to a continuous increase in electronic data, as ever new technologies are employed, which can collect, store and share it. A lot of this data is relevant to a person's health. This goes far beyond mobile devices, which already now can record electrocardiograms, measure blood pressure or body temperature. It also covers domains such as imaging, genomics and health information systems. If more data becomes available electronically and is interconnected, artificial intelligence (AI)-based technologies can gain valuable insights from analysing such diverse information. They can significantly contribute to transforming our healthcare system from managing towards preventing diseases, thus rendering it much more sustainable.

However, digital transition of conventional healthcare systems is far from trivial. Usually, healthcare systems form a highly complex network of different stakeholders. In it, the scope of electronic medical recording, data standardisation and interoperability remain key issues. While facing similar demographic and healthcare challenges, western countries show varying degrees of healthcare digitisation, as will be exemplified by a closer look on Germany and Japan.

### Digital healthcare landscape of Germany

### Demographics and current state of healthcare digitisation in Germany

In Germany the proportion of citizens aged 65 and above has almost constantly increased over the last 50 years while birth rates remained low at an average 1.4 births per woman.<sup>1,3</sup> Akin to Japan, Germany is well on its way to becoming another 'super-aged' society and its healthcare system faces similar challenges. According to a recent study which analysed the level of healthcare system digitisation in 14 EU- and 4 non-EU-countries (Canada, Australia, Switzerland and Israel), digital healthcare in Germany is in an early developmental stage.<sup>6</sup> In an Electronic Medical Record Adoption Model (EMRAM) analysis based on data from 2013 to 2015 Germany scored 1.8, which is below the EU-average of 2.8 (figure 1).<sup>7</sup> The EMRAM measures the adoption and utilisation of electronic medical records (EMRs) required to achieve a paperless environment to support optimised patient care.<sup>8</sup> The score consists of eight-stages, from 0 as worst to 7 as best.



#### **EMRAM Score (Average)**

Figure 1: Electronic Medical Record Adoption in Europe: country comparison of EMRAM-Scores<sup>7</sup> (figure taken from [9])

Despite an hitherto rather reluctant attitude towards healthcare digitisation, Germany ranks one of the largest national healthcare markets among the OECD countries with a national health expenditure of 11.2 percent of the GDP<sup>10</sup> and its digital health sector shows a positive development, especially in the mHealth domain.<sup>11</sup> In addition, revenue forecasts for digital healthcare solutions in major chronic diseases, such as diabetes and heart failure, are positive.<sup>12</sup> In the last decade many technologically driven healthcare solutions (e.g. ambient assisted living, telemedicine or online portals for self-diagnosis and self-treatment) have been developed while they have been implemented on a small scale thus far.<sup>13</sup>

The HIMSS Annual European eHealth Survey indicated that challenges in German healthcare digitisation concern funding, interoperability standards, a low degree of digitised patient data compared to other EU countries as well as little governmental support for digitisation incentives.<sup>14</sup> Indeed, interoperability is aggravated by the fact, that in German electronic data is currently bound to many different healthcare sectors with little data standardisation. Besides, concerns regarding data security and privacy of sensitive information are a key obstacle which delays implementation of data-driven healthcare solutions. German Federal Ministry of Health (BMG) has recently underscored that the national government is aware of the challenges and has signalled willingness to promote transition towards a more digitised healthcare system.

#### German digital health incentives

In 2010, the BMG launched an eHealth initiative to connect to relevant stakeholders, identify obstacles and develop solutions to implement digital healthcare. The initiative's major achievements were a national portal for telemedicine (which contains information about more than 200 different telemedical projects) and a planning study on interoperability (suggesting approaches to overcome interface issues). In 2016 the German government passed an eHealth law, serving as a formal road-map to implement digital healthcare. One of its main goals is to accelerate market entry for digital solutions. Following this law, video consultations to certain specialist groups and medical indications were introduced in April 2017. Since 2018 remote treatment is also available in Germany. In the same year the BMG established a healthcare digitisation unit. Its task is to coordinate and support EMR implementation. Scheduled for 2021 is a nationwide personal health record (PHR) which is currently in its testing phase. Several different PHR approaches are currently under way and data integration remains an unresolved issue.

Despite these governmental incentives, a key obstacle towards healthcare digitisation is, that all measures still lack a higher-level strategy or central coordination. A national digital-health authority with compelling and proprietary budget is needed to foster healthcare digitisation and work out overall mandatory goals, guidelines and timelines.

### Digital healthcare landscape of Japan

#### Demographics and current state of healthcare digitisation in Japan

Japan's health expenditure currently accounts for 10.9 percent of the GDP which ranks one of the largest national healthcare markets among the OECD countries.<sup>15</sup> It is the fastest ageing nation in the world, and health expenditure is expected to grow. Although facing similar challenges in its healthcare system, Japan is ahead of Germany in terms of healthcare digitisation. With a proportion of 93.8 percent, almost every Japanese hospital uses electronic invoicing.<sup>16, 17</sup> Of the larger hospitals (>400 beds) over 75 percent work with EMRs and over 80 percent use electronic ordering systems.<sup>18</sup> In Japan, national insurance covers costs for telemedicine of several diseases. Similar to Germany, the country's digital healthcare market volume is constantly expanding with an annual growth rate of at least 1.2 percent from demographic facts alone.<sup>19</sup> The electronic health sector is estimated to grow annually by 11.2 percent until 2020, largely driven by an increasing number of wearables and Internet of Things (IoT) applications and continuing medical data acquisition.<sup>17</sup>

#### Health and medical care data of Japan

In part because of universal healthcare coverage for the entire population, Japan has quantity and quality health and medical care related data collected through its healthcare system with the universal coverage for all the population. The data can be broadly categorized as: **1** health data, **2** medical care data, and **3** nursing care (long-term care, LTC) data.

**1** Health data collected through regulatory annual health check-ups independent of clinical conditions, which will make chronological and health data available for individuals. In addition, as of the end of FY 2017 (March 2018), approximately 260 million results of the specific health check-ups for the population aged from 40 to 75 to prevent life-style diseases, are accumulated in the National Database of Health Insurance Claims and Specific Health Check-ups of Japan (NDB).

**2** Medical care data, such as healthcare insurance claim information, which the universal coverage has enabled the government to collect. The number of the healthcare insurance claims accumulated in the NDB from 2009 is approximately 15.3 billion (as of the end of FY2017, March 2018).

**3 LTC data** collected through the country's universal Long-Term Care Insurance (LTCI) System; the data includes LTCI claims and certification information for the eligibility of the nursing care under the LTCI System. The data for the LTCI claims and the certification information accumulated amounts to approximately 970 million in number as of the end of FY2017 (March 2018).

The health-related information has become managed as a database by public-sector organisations over the past decade (figure 2). Private-sector organisations have also developed such databases.

Database Name	NDB (National Database of Health Insurance Claims and Specific Health Check-ups of Japan)	Comprehensive Long-Term Care Insurance (LTCI) Database	DPCDB (Diagnosis Procedure Combination Database)	National Cancer Registry Database
Data Source	Health insurance claims, specific health check-ups, specific health guidance	LTCI claims, LTC certification information	DPC* information	Cancer registry information
Major Data Items	Disease name covered by insurance, medication, health check-ups results	LTC services provided, types of certification	Disease name, patient conditions, medical facility information	Medical treatment, outcome
Secondary Use By Third Parties	Allowed since 2013	Allowed since 2018	Allowed since 2017	Allowed; details to be specified
Started In	2009	2013	2017	2016
Database Name	Database for Patients with Designated Intractable Diseases	Database for Children with Specified Chronic Diseases	MID-NET (Medical Information Database Network)	
Data Source	Clinical questionnaire information	Medical opinion information	EHR, health insurance claims	
Major Data Items	Disease name, patient conditions, diagnostic criteria	Disease name, age at onset, test results	Prescription information, injection information, test results	
Secondary Use By Third Parties	Not allowed; feasibility under study	Not allowed; feasibility under study	Allowed since 2018	
Started In	2017	2016	2011	

\* DPC: Diagnosis Procedure Combination, Japan's original patient classification system

Figure 2: Major health related databases administered by public-sector organisations (modified based on material of Ministry of Health, Welfare and Labour of Japan<sup>20</sup>)

#### Japanese digital health incentives

In response to the ageing population, the Japanese government has developed a centralised approach to promote next generation healthcare policies in order to create healthy long-life society. As a cross-ministerial organisation, the 'Headquarters for Healthcare Policy' was established in 2014, with Prime Minister Shinzo Abe as its director general (figure 3).

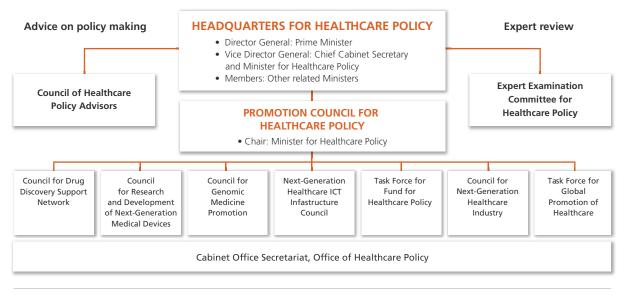
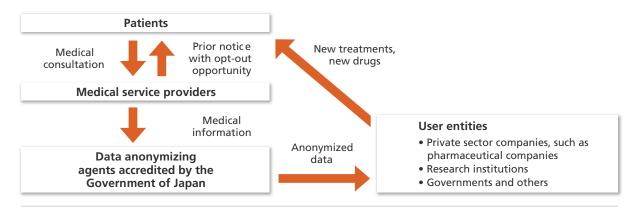


Figure 3: Cross-ministerial organisation for promoting next-generation healthcare (modified based on material from Headquarters for Healthcare Policy<sup>21</sup>)

They plan to utilise diverse health related data, as well as establishing technical prerequisites, rules and standards to link data via information and communications technology (ICT) and create a more patient-centred, next-generation healthcare system.<sup>22</sup> Key policy initiatives include:

### Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development:

In 2017 the Japanese parliament passed the bill for 'Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development', which came into effect in 2018. The act aims to create a system to allow utilisation of anonymously processed medical information by third parties such as research institutions, government agencies and privatesector companies and promote advanced R&D and new industry creation (figure 4) in order to create healthy long-life society, while safeguarding patient's privacy. To fulfil the high data security requirements, the Japanese government authorises only accredited corporations to gather medical records from different medical service providers. It is a voluntary system which medical service providers are able, but not required, to take part in; patients are informed ahead of data provision to the accredited agency so that they can opt-out if they refrain from the provision.



**Figure 4:** Structure of the Act on Anonymously Processed Medical Information to Contribute to Medical Research and Development (modified based on material from the Office of Healthcare Policy <sup>23</sup>)

#### Establishing a platform for integrative medical data analysis as big data

The Japanese government is establishing a data analysis platform through which the governments, insurers, researchers, private-sector companies, and others will be able to consolidate the data for health, medical care, and LTC and analyse it as big data. The Integrative analysis will make available for two databases at first, NDB and LTCI database (Comprehensive Long-Term Care Insurance Database). Start of operations is anticipated in FY 2020.

#### Promoting genomic medicine development using data

The Japanese government is promoting data aggregation including genome for developing innovate therapies for cancer, such as drug discovery and diagnoses technologies. Center for Cancer Genomics and Advanced Therapeutics (C-CAT) was established in June 2018, to aggregate and manage nationwide information on genomic medicine and implement a system to promote appropriate use of the information for developing new cancer medicine. The C-CAT aggregates cancer genome information generated through the gene panel testing using Next-generation Sequencers developed by the National Cancer Center Japan and others, which have become covered by national health insurance since June 2019. The coverage will help the C-CAT aggregate more data regarding cancer genome information.

### Digital healthcare ecosystem in Japan

#### Digital healthcare market in Japan

There is a thriving business scene for digital healthcare in Japan. A recent market report <sup>24</sup> estimates the market size of Japan's health tech and healthcare solutions in 2018 had grown to JPY 224.8 billion, +9.4% increase compared to the previous year. The same report forecasts the market will grow to JPY 308.3 billion, +50.0% increase compared to 2017.

The investment by venture capitals to healthcare start-up companies is also increasing. The total domestic investment by Japanese venture capitals in FY 2018 amounted to JPY 164 billion, 20.4% increase compared to FY 2017. Biotech, medical and healthcare sectors account for 18.9% of the FY 2018 investment, the second largest following the IT sector. Health tech solutions are among remarkable markets, increasing by 159% in 2016, compared to the previous year.<sup>25</sup>

For example, FiNC Technologies Inc., a Japanese start-up company which develops health management application using AI, collected funds of more than JPY 2 billion from Japanese large companies, such as Meiji Yasuda Life Insurance Company and Rohto Pharmaceutical Co., Ltd., in 2017. The company also raised funds from Teijin Frontier Co., Ltd., a major Japanese textile manufacturer, in 2018, to develop solutions to sleep disorders, using AI and sensor technology. Another example is LPIXEL Inc., which is developing AI medical image diagnostic support technology using a deep learning approach with image data including magnetic resonance imaging (MRI) data. The company raised about JPY 3 billion in 2018, from Japanese major companies such as Olympus Corporation and Fujifilm Corporation.

Among these may be Preferred Networks, Inc. Japan's well-known unicorn company also focuses on the healthcare sector, specifically genomics analysis, medical image analysis, and compound analysis, by using a deep-learning AI approach. Since its launch in March 2014, Preferred Network has been funded several times by major Japanese companies, for example, approx. JPY 10.5 billion from Toyota in October 2017, more than JPY 2 billion from Hitachi, Mizuho Bank and others in December 2017, and approx. JPY 900 million from Chugai Pharmaceutical and Tokyo Electron in August 2018.

#### Government initiatives to support digital healthcare business creation

The Japanese government has been working on not only creating a next-generation healthcare system, but also supporting a business environment creation which promotes private-sector investment and innovative product/service development in the healthcare sector to adequately respond to the needs of an ageing society.

#### Regulatory sandbox system

The government has introduced the regulatory sandbox system to accelerate the introduction of new business models and innovative technologies since June 2018. The system is aimed at helping companies in and outside Japan conduct pilot projects quickly by easing regulations for a limited period of time and scope and building up data that can lead to change in regulations. 8 projects in the fields of IoT, online medical consultations, and FinTech have been certified as of July 2019. <sup>26</sup>

#### Healthcare Innovation Hub

Healthcare Innovation Hub (InnoHub) is a one-stop support centre for Japanese and foreign start-up companies related to healthcare and life-science. It started operations in July 2019.

#### Well Aging Society Summit of Japan

The government organises many start-up pitch contests in Japan open for both Japanese and foreign companies. One of the most notable ones is that at the Well Aging Society Summit Asia-Japan, where healthcare leaders from around the world gather and discuss shared issues of an ageing society and innovative solutions. This year's Well Aging Society Summit Asia-Japan will be held in October in Japan.

#### Japan's business environment and market potential

The Japanese approach to promote the use of data and technologies for creating a next-generation healthcare system makes Japan a highly attractive market for investments and collaborations. In terms of market openness Japan is comparable to many European countries, in that threats, such as expropriation, equity caps or forced licensing, do not exist. Globally, Japan ranks well regarding indices for rule of law, product market regulation and digital trade restrictiveness.<sup>27-29</sup> In addition, German businesses can benefit from the EU-Japan Economic Partnership Agreement (EPA), which came to a successful conclusion in December 2017 and was signed in July 2018. The EPA helps to eliminate or reduce tariffs and agree on norms in areas such as digital technologies, thereby reducing regulatory uncertainties. As measured by the current health expenditure per capita Japan is the largest accessible market in Asia, surpassing even countries such as Korea and Singapore (figure 5).<sup>30</sup> Given the country's huge amount of high quality medical data, tech-friendly citizens and very good health sector IT infrastructure, Japan is an ideal test bed, especially for digital healthcare.



Figure 5: Health expenditure per capita in 2016 (current US\$), modified from [30]

# Collaborations to promote digital healthcare with Japan

#### Digital healthcare collaboration cases

The Japanese government and other national stakeholders follow an open-door policy for international collaborations. Japanese local governments, research centres and companies already started to create loose alliances with foreign companies to jointly tackle healthcare challenges.

#### Case 1 - Care plan development using AI with Toyohashi city

Activity Recognition Inc., a US company and spin-off from Stanford University collaborated with the Care Design Institute (CDI), a Japanese healthcare provider, and Toyohashi city. The aim of this partnership was to improve health and independence of elderly citizens by providing more affordable and effective care plans as well as helping care professionals give their patients a more personalised and improved quality of care. Activity Recognition's role in this collaboration was to provide a state-of-the-art machine learning solution which processes patient health records and proposes optimal care plans. The healthcare provider CDI provided a dataset of approximately 100,000 health records from Toyohashi citizens. The collaborators commenced a pilot study which turned out to be successful. As a result, the city of Toyohashi adopted the AI system for further study. <sup>31</sup>

#### Case 2 - Healthcare point system development for Japanese healthcare insurer

Fitbit, a US wearable company, has collaborated with a subsidiary of Fujitsu, Fujitsu FIP, which has provided a Japanese insurer with a health point management system for its insured members since 2017. This system collects activity volume data automatically through Fitbit wearable devices and convert them with each user's health and medical check-up information held by the insurer to health points for supporting insured member's health with data and incentives. The government published guidelines in 2016 to promote such a health point system in which health insurance providers can offer incentives to insured members, leading to improved health. Since then, more and more health insurance associations and municipalities have been working on such a system to give incentives to those who exercised or had a check-up, which can be exchanged to goods and gift cards. <sup>32</sup>

#### **Opportunities for German businesses and organisations**

The examples above show, how the Japanese market openness and availability of real-world medical data offers great potential also for foreign businesses and organisations active in data and technologies. In practical terms, this applies to German businesses and organisations, as well as some of our very own projects at the Digital Health Center of the Hasso-Plattner-Institute or the data4life GmbH, supported by the Hasso Plattner Foundation, in which we develop digital solutions to improve the management of chronic diseases. The large electronic health records data across hospital, ambulatory and long term care sectors available in Japan are of extraordinarily high value to us, as they allow development and testing of digital solutions to support continuity of care and value-based healthcare models, which is considerably more challenging in Germany at this time. The Hasso-Plattner Institute, as well as other German institutions and businesses can anticipate productive cooperation opportunities with potential Japanese partners, focused on advancing digital health solutions in ageing societies.

A key to a successful collaboration for German business is to ensure that their approach meets the Japanese regulatory frameworks prior to starting a collaboration, especially regarding data privacy and security. It is important to be fully transparent and to disclose in detail, how the provided medical information is analysed, stored and shared by the company's or organisation's product. One should also bear in mind Japanese business practices and cultural differences with Germany in the context of user experience and performance, while keeping an eye on our shared issues between the two countries for creating a sustainable healthcare system for an aging society, using data and technology.

### Conclusion

Data related to health and medical matters covers a wide range, from regular health check-up results, medical treatment and prescription information, to vital data generated by patients or customers from day to day via wireless mobile devices. This continuous growth in data volume can be a valuable source of information, not only to improve medical care and create new treatment but also to learn how to prevent healthy citizens from diseases. The prerequisite, however, is that innovative solutions have broad data access. Only then AI-based technologies can learn and draw relevant conclusions.

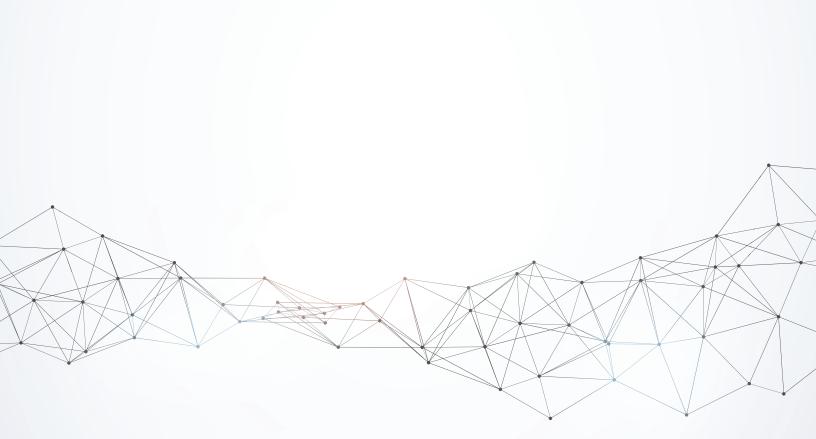
It is remarkable to see how the Japanese government is setting up a system allowing utilisation of medical data by research institutions and private-sector organisations for innovation and new business creation while at the same time meeting high data security requirements. The liberalisation of the Japanese digital healthcare market has paved a way to make use of the valuable data resources for businesses with foreign companies and/or organisations. In a globally connected world we depend on foreign investments and collaborations to accelerate the transition towards digital healthcare.

With our own country lagging, it is the ideal moment for German businesses and organisations to consider investment and collaboration with Japanese stakeholders. The country is a blueprint for many other soon-to-be super-aged societies. The Japanese and the German healthcare system, will considerably benefit from such collaborations.

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HPI Digital Health Center Potsdam Campus Griebnitzsee | Universität Potsdam

Prof.-Dr.-Helmert-Strasse 2 - 3 14482 Potsdam

- **T** +49-(0)331 5509-0
- E hpi-info@hpi.de
- W https://hpi.de/digital-health-center/home.html