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Chapter 2 - I

# Is the Future of Digital Platforms a Bright One?

## : Proposals for open innovation and governance

Toshio Miyata*

In the country of Japan, which is experiencing a rapidly aging population that is unprecedented in the world, people are questioning whether the healthy life expectancy can be extended further. As this population decreases due to aging and a low birth rate, the balance between the funding source of social security and the percentage of the population that is of working age has been disrupted (Figure 1), and the sustainability of the nation's unparalleled universal healthcare system is now uncertain.

At the start of the Reiwa era from 2019, the healthy life expectancy, which is the period in which an individual can live with no restrictions on their daily life, was estimated to be 8.73 years shorter than the average lifespan for men and 12.06 years shorter for women.[1] There are now calls to close this gap in order to make the universal healthcare system more sustainable and to create a society where people can live healthy lives for as long as possible. One innovative solution that has been gaining attention for tackling this is the idea of healthcare services that arise from the creation of database platforms and act as a sort of one-stop shop for using biometric and other data to prevent, treat, and follow up on illnesses. But a variety of problems have been identified when it comes to using this sort of data, and progress has been slow. Japan in particular is lagging behind the rest of the world, and a speedy solution is needed.

Self-care and self-medication are two important points when considering how to extend healthy life expectancy. The World Health Organization (WHO) defines self-medication as "taking charge of one's own health needs and treating light physical ailments by oneself." Self-care is a broad concept that includes establishing and maintaining a healthy body to prevent illness, recognizing the significance of one's own behavior, and many other areas such as sanitation, nutrition, lifestyle, environment, socioeconomics, and self-medication.

But from the perspective of promoting and maintaining the health of ordinary citizens, self-medication and self-care aren't making much progress in Japan, despite increased interest in self-care and more oppor-

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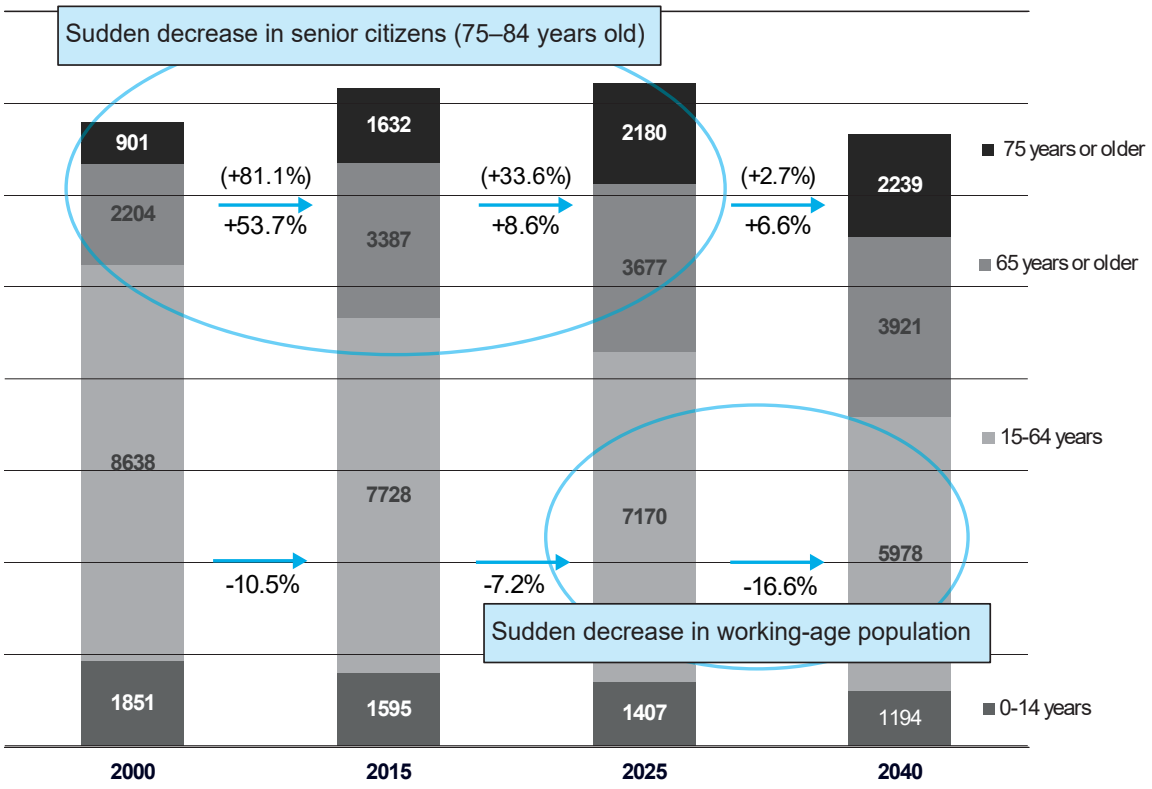
1 See the MHLW Grants System "Healthy life expectancy: Analyzing the causes of regional disparities and examining the effectiveness of health-promotion activities" (study representative: Ichiro Tsuji ).

**Figure 1: Changes in population structure through 2040** [2]




(Population beyond 2025 relies on statistical projections)

tunities for it. For the average citizen, deciding when to go to the doctor and when to practice self-care or self-medication is difficult, and in general, the free access to universal healthcare makes people quick to head to the clinic. The Japanese government has implemented a number of policies, such as promoting a switch to over-the-counter (hereafter "OTC") medicine, encouraging people to have a family pharmacist by establishing an official system for "health-support pharmacists," and creating tax regulations for self-medication (a deduction for medical expenses was added in 2017 to promote self-medication). Nevertheless, many people currently utilize medical facilities even for minor illnesses.

In addition, the risk of developing cancer is said to drop by 43% for men and 37% for women if they simply adopt the five healthy habits of assessing their diet, maintaining a suitable body weight, abstaining from smoking, reducing alcohol consumption, and exercising. Considering that preserving and improving the health of employees is an investment that provides future benefits to companies, the Ministry of Economy, Trade, and Industry (hereafter "METI") is now promoting a strong implementation of "health management" that approaches health from an operational perspective. This means that we cannot simply focus on the development of genome therapies and other new treatments—we must also promote digital transformation (DX) and the digitization of daily personal data related to sleep patterns,

2 Created by the author from the MHLW's "7th Feedback Session for the Eighth Healthcare Plan (March 4, 2022) — Document 1, Eighth Plan: Regarding Community-Based Medicine etc." (https://www.mhlw.go.jp/content/10800000/000911302.pdf). Source: Ministry of Internal Affairs and Communication's "National Census" and "Population Estimates"; National Institute of Population and Social-Security Research's "Future Population Estimates for Japan — 2017".

stress levels, diet, exercise, and other areas into a public health record (PHR) so that the information can be visualized and used to facilitate the modification of behavior. As Japan faces its future as the world's top super-aged society, it will need to draw on some of the models seen in other countries and industrialize its medical services in order to extend the healthy life expectancy while simultaneously generating new economic strength.

## 1 Specific actions

### (1) Public-private collaboration initiatives

In 2015, three stakeholders—the business community, the medical industry, and municipal governments—launched the *Nippon Kenko Kaigi* with the goal of extending the healthy life expectancy and making medical costs more reasonable. This organization was formed in conjunction with the Ministry of Health, Labor, and Welfare (hereafter "MHLW") and the METI for the purpose of promoting private initiatives related to advanced disease prevention and healthy living, led by some of the top people in business, medicine, and local government. I have also served as an advisor on the Council's action committee. The Japan Health Council has also adopted the "Declaration for Building Healthy Communities and Workplaces 2020" (2015), which consists of eight statements that include points about health management.

Declaration for Building Healthy Communities and Workplaces 2020 (2015)

Statement 1: Get at least 800 municipalities to promote incentives for disease prevention and healthy living to citizens.

Statement 2: Get 800 municipalities to implement programs for preventing the worsening of lifestyle diseases by coordinating with family doctors etc., then form two wide-area alliances. When doing so, aim to work with the Diabetes Prevention Council etc.

Statement 3: To prevent diseases and enhance people's health, have the insurance boards from all 47 prefectures implement activities related to prevention, in coordination with communities and workplaces.

Statement 4: Get at least 500 companies (corporations) to implement health-management programs in conjunction with health-insurance associations and other insurer groups.

Statement 5: Get at least 10,000 companies to implement health announcements etc. by obtaining the support of the Japan Health Insurance Association, the Chamber of Commerce and Industry, etc.

Statement 6: Get 100% of insurers to provide their customers with their own medical and health data in a format that is easy to understand. When doing so, aim to fully utilize information and communication technologies (ICT).

Statement 7: To improve the quantity and quality of businesses that offer planning and implementation

services for disease prevention and healthy living, build a framework for evaluation and certification then get at least 100 healthcare companies to achieve certain standards established through insurer recommendations etc.

Statement 8: Work to improve the usage of generic medications by getting all insurers to recommend them and requiring the government to ensure their quality and stable supply.

Statement 2 is about increasing the number of municipalities with initiatives for preventing the worsening of lifestyle diseases. If we can extract the medical and prescription data held by insurers for residents who won't visit the doctor even though they received a suspicious diagnosis—or those who quit going to treatment partway through—then use it to encourage them to visit the doctor and control the illness before it gets worse, we will be able to reduce the risk of it worsening, avoid the cost of advanced medical procedures, and extend the healthy life expectancy.

**Figure 2: Declaration of Action 2025: Five Initiatives for Building Health (Outline)**

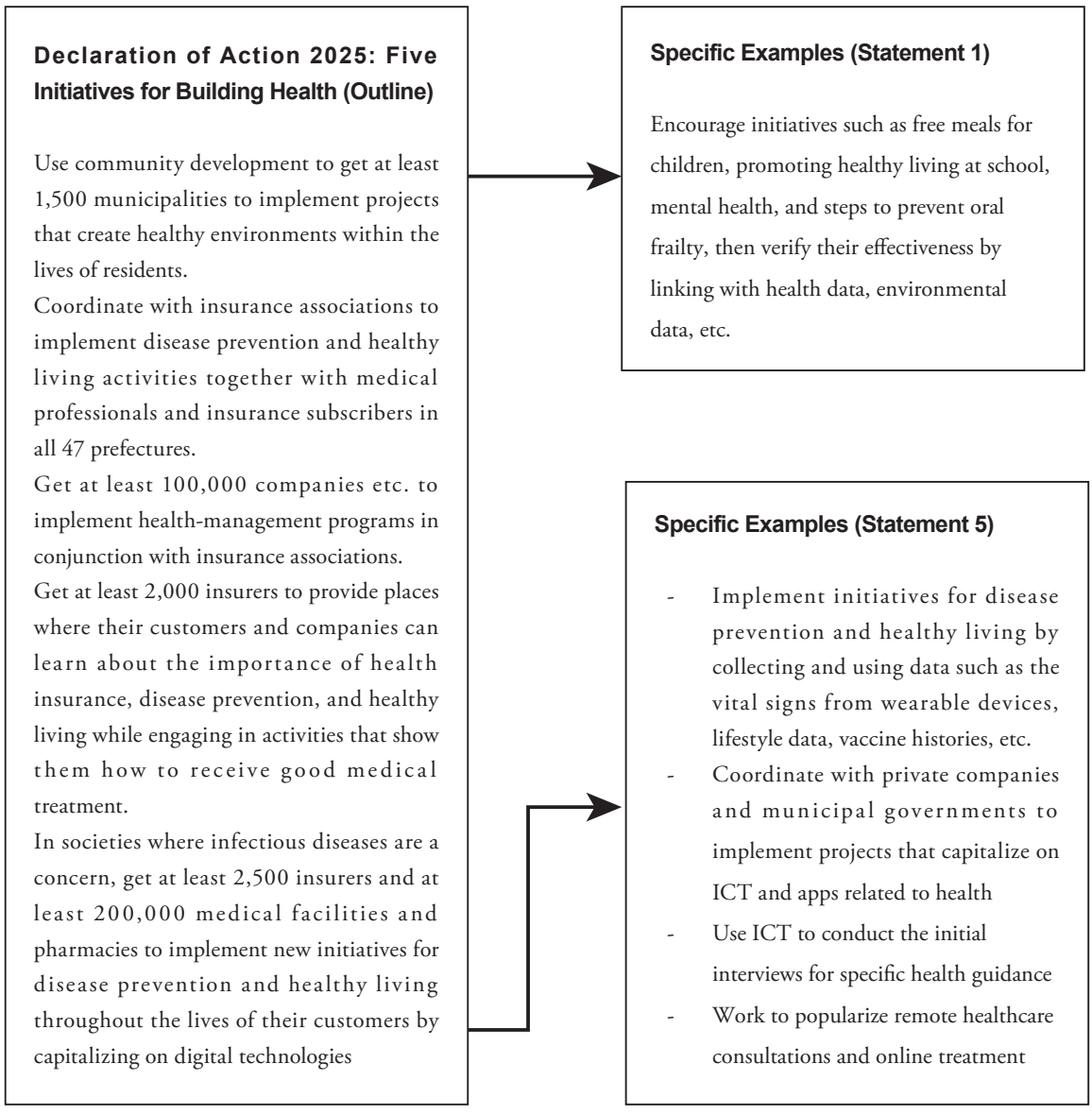


**Figure 3: Overview of "Ken Compass" Apps** [3]

**"Ken Compass"**
Release Date: June 26, 2017 Supported OS: Android / iOS
Available To: Everyone Price: Free
Language: Japanese

In addition, five goals for 2025 have been added; Statement 1 promotes the linking of health data with the living-environment data of municipalities, while Statement 5 advances disease prevention and healthy living by utilizing data obtained from wearable devices, lifestyle data, vaccination information, etc. (Figure 2).

## (2) Self-medication Apps.

In response to the sluggish adoption of self-care and self-medication in Japan, the author released a self-medication support app called "Ken Compass" in 2017 (Figure 3).

Medical associations are facing significant challenges. They are telling people to visit their family doctors if they feel sick, but the sheer volume of data available online now makes it difficult to find the right information, and many people fall victim to shady health websites and lose large sums of money. Within this context, Ken Compass is a self-medication app created under the guidance of physicians and pharmacists while carefully coordinating with government agencies and medical associations. Although Japan lags significantly in this field compared to other countries, Ken Compass did see an increase in users during the COVID-19 pandemic, so more residents now have access to accurate information. Self-medication apps face a few challenges:

3 Source: Ken Compass (https://Ken Compass.co.jp/app-lp/, last access in November 2024).

- They must incorporate as much expert knowledge of medicine and treatment as possible, but they cannot be designed in a way that qualifies as the act of medical treatment itself (doing so would violate the Medical Practitioners' Act and the Pharmaceuticals and Devices Act).
- They must be represented in advertising etc. in a way that does not violate the Pharmaceuticals and Devices Act, the Health Promotion Act, the Act against Unjustifiable Premiums and Misleading Representations, or other legislation.

Ken Compass solves these challenges. The COVID-19 pandemic also led to the creation of many different healthcare services, and big changes have gradually taken place in Japan's digital healthcare field.

### (3) Online medicine

The author have also worked to popularize the online treatment process. Online treatment is when a patient and doctor in different locations connect through the video-conferencing features of a smartphone or PC to engage in real-time healthcare. Known in the past as "remote healthcare," online treatment was previously only permissible in cases where it was required for people on remote islands or in other distant locales to receive medical care.

But in 2015, the MHLW effectively lifted the ban with a notice declaring that online treatment was "not restricted to remote islands or backcountry areas," and health insurers were also allowing follow-up examinations to be conducted via telephone. Then, in 2018, a revision to the system for medical-service payments officially made online treatment eligible for insurance coverage. Except for special cases like smoking-cessation clinics and prescriptions for emergency contraceptives, online treatment has certain restrictions—for instance, the initial examination must typically be done in person. A 2019 survey conducted by the MHLW thus found that only 24.3% of hospitals and 16.1% of clinics were offering online treatment. However, these restrictions were greatly relaxed due to the coronavirus pandemic, making online treatment available even for the initial examination, which was previously restricted to the follow-up exams of patients with stable chronic illnesses. Demand for online treatment continued to increase as the nation scrambled to stave off the COVID-19 infection and prevent the collapse of its healthcare system due to hospital-acquired infections. On April 10, 2020, the MHLW issued a notice that approved online treatment for initial examinations, including those involving people with no previous history of medical exams. The requirement for face-to-face visits with drugstore pharmacists was also removed, allowing medical facilities to submit prescriptions to pharmacies via fax or similar methods. And after a patient has received usage instructions from a pharmacist online, their prescriptions can now be delivered to their home by the pharmacy.

During an initial online examination, taking the time to gather data such as the patient's prior medical history and prescription usage is especially important, and the question of how to acquire such patient data is even more so. In our experience, however, initial online exams are hindered by the difficulties in obtaining a patient's prescription history and the results of blood tests and health check-ups conducted at other facilities. We may be able to streamline the initial online exam process by utilizing the national ID number ("My

Number") system to extract this sort of data. But there are several challenges, including the fact that pharmacies are closed in the middle of the night; the question of how to ensure communication between medical facilities when a patient's symptoms worsen after they receive online treatment; and issues with people impersonating patients, reselling their prescriptions, or engaging in cyberattacks. Solving these will require experts from not only medical science but many other fields to coordinate in establishing some ground rules.

Moving forward, we expect that new technologies in sensing, monitoring, and artificial intelligence will enable the creation of new healthcare platforms that hybridize with in-person medical treatment. If the industry moves to ultra-high-resolution 8K images, then we may even be able to treat dermatological issues, which is currently not possible due to the limitations in image technology. Right now, doctors can't typically listen to the chests of their patients with a stethoscope during online treatment sessions; but if they could easily listen to heartbeats in real time, the quality of such online treatment would also improve. And the global race to develop such technologies is intensifying.

### (4) Digital health innovations using data

The Tokyo Metropolitan Government is conducting a proof-of-concept trial known as the Mobile ICU/ER Project that installs equipment for performing electrocardiograms, ultrasounds, blood analyses, etc. within ambulances. This equipment is used to measure the vitals of patients during transport then transmitted in real time to the hospital so that treatment can begin immediately upon arrival. Selected by the government of Tokyo for its "Project Proposal System for University Researchers," the Advanced Hospital Transport System Project (2019–2021) utilized mobile ICU/ERs to construct an advanced transport system led by a medical team for emergency patients who could not be cared for at their current medical facilities as well as those whose condition had worsened during their hospitalization.

This project was a collaboration between not only government and academia but also various private companies such as Toyota Customizing & Development, Sysmex Corporation, GE HealthCare, and Nihon Kohden. Industries, universities, and government agencies worked in tandem to advance digital transformation (DX) by linking with data in the medical devices aboard ambulances, and the effort has conceivably contributed to solving some of the challenges faced by Tokyo's medical and emergency healthcare systems. The Tokyo Metropolitan Government is now considering how to apply the results of this project to a full-scale deployment in the future.

There are many other initiatives found throughout the industrial world. For example, there are apps that help women manage their periods by entering information about their pre-menstrual syndrome (PMS) symptoms and menstruation cycles. This allows them to manage data about their daily condition as a PHR. Such apps have become quite popular among young women, and future integration of the data accumulated by private companies with the data held by entities such as insurers and medical institutions should lead to the creation of new "FemTech" services for them.

In the future, PHRs will connect the data of hospitals and insurers to municipalities and businesses, which could create new evidence for the effectiveness of yoga, for a supplement that lacks clinical validation, etc. As for the government, the MHLW will have to coordinate with the METI as well as the Digital Agency

in support of this transition. In terms of the secondary usage of data, we must eliminate the need for consent during acquisition and revise the restrictions on its usage (export regulations).

And on the device side, we can do like Apple watch did when they created the new word "blood oxygen wellness" to replace "blood oxygen saturation," thus bypassing the regulations in the Japanese Pharmaceuticals and Devices Act and allowing the average consumer to use the device as a monitoring (non-medical) device. As cases like this increase in number, people are focused on the expansion of healthcare services that do not involve medical devices. However, ensuring the effectiveness and safety of services that bypass medical device approval remains a challenge.

We also need to use real-world data like the results of health check-ups, prescription information, and DPC data, and we need to change electronic health records (EHRs) in a way that advances clinical epidemiology. The government is also working on these areas. And it's not just the big hospitals—we must make strides in connecting the small and medium clinics and infirmaries so that their medical data can be used, too. However, the cost of sharing EHRs with external entities has been a significant bottleneck to progress. EHRs aren't being used much at all in infirmaries, either, so digitizing that data is another big hurdle. With EHRs, the government doesn't regulate the pricing for payments like it does for drugs and medical devices, so costs are currently one thing that is pressuring the managers at medical facilities. This reveals that EHRs need to be reformed as soon as possible.

What we need are electronic health records that private clinicians and smaller facilities can download free of charge and use immediately. Building an infrastructure that facilitates this will allow us to collect post-release clinical data from companies that make drugs or medical devices while utilizing real-world data to control development costs and build an ecosystem. In fact, the MHLW is trying to encourage the development of such EHRs. Simultaneously advancing DX for medical payments should also allow for the creation of feedback regarding everything from the treatment outcome to the payment process.

## 2 Conclusion

A streamlined production system for comprehensive healthcare services is hindering advancement in Japan. Some of the challenges are the lack of a hierarchical framework for the country's government ministries and municipalities as well as the insufficient links between the various departments and subsidiaries of major corporations. It's easy to make a specialized service for a limited domain, but much more difficult to make a broader service that connects laterally. Based on my own experience as an administrative official, I feel that I'm probably biased in my impression that creating something new which overcomes the regulatory hurdles and organizational obstacles faced in Japan would be a tremendous task. Even Japan's university hospitals formerly emphasized fundamental research more than clinical studies, and there was a sense that the latter simply couldn't be done in Japan. But the tide is now turning, and clinical studies are starting to be seen as important. As the world changes, so will Japan. We shouldn't expect it to remain the same. Rather, we must involve the various parties and form a strong leadership to

propel the needed changes forward.

So, what should digital healthcare platforms look like? There are two ways of approaching the question: starting on the clinical side then expanding to the non-clinical side, and vice versa. The platforms should be developed by combining both approaches. In Japan, hospitals and clinics are non-profit organizations. To create new platforms, then, it is imperative that we not only enact regulatory reform but also reexamine our legal frameworks rooted in historical and societal norms as we plan for increased collaboration between for-profit and non-profit entities and work to achieve a solid common ground between the two. And as the young physicians with innovative mindsets continue to flourish within the world of medicine, cooperation between different industries such as banking and private insurance should continue to grow. But activating this sort of open innovation will require even more leadership training within the field of healthcare. It's not about profit versus non-profit—the critical thing is to create designs that incorporate all the various stakeholders in a cyclical fashion and educate people at the same time.

Also, the popularization of self-care apps like Ken Compass as well as online treatment through medical facilities will change the specific responsibilities of stakeholders as healthcare services escape the confines of hospitals and enter our everyday lives. More discussion with legal experts is needed regarding the future state of corporate governance, since the relative importance of manufacturers will increase when managing software programs that incorporate artificial intelligence. For example, healthcare apps that use generative AI might convince patients to stop visiting their doctors and ignore their illnesses. So, the fact that medical services and the responsibility for them will continue to expand beyond the boundaries of medical facilities is a significant challenge for the administrators of such institutions. We need to properly divide the responsibilities among the private companies within the healthcare space while developing a framework that incorporates things like A.I. and online treatment to not only make things more efficient but also involve doctors in the entire process. Japan and the rest of the world must undergo a paradigm shift from treatment that a doctor independently selects to a more patient-focused system as the relationship between physicians and patients evolves. We should monitor how society reacts to these changes as we engage in open dialogue and encourage cooperation with an eye toward diversity and inclusion.

We may now be in an era that requires stricter governance of for-profit medical practitioners. As with the Act on Ensuring the Safety of Regenerative Medicine, legislation related to online healthcare could be required moving forward. If we don't come up with suitable penalties for the for-profit physicians treating cases that aren't covered by insurance, we won't be able to control medical costs. Therefore, more discussion between industry, government, and academia is needed to avoid stagnated growth in the burgeoning field of healthcare. The health of some individuals has even been damaged by drugs prescribed during online exams for the purpose of weight loss. If we can build e-health DPFs that drive innovation in medicine, we can stabilize the sustainability of Japan's universal healthcare system, create new industries, and hopefully contribute to the development of universal health coverage throughout the world.

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