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# Survey for Government Policies Regarding Strategies for the Commercialization and Globalization of Digital Therapeutics

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**Purpose:** This study was conducted to build a direction for government policies regarding strategies for the commercialization of digital therapeutics in Korea, as well as its globalization.

**Materials and Methods:** The study included 37 participants from the Korea Digital Health Industry Association (KODHIA). The data was based on a survey conducted in 2020 targeting employees of companies engaged in the digital health industry in Korea. Participants were asked about their involvement in product development of digital therapeutics and their opinion about the growing motivator for digital therapeutics in Korea and the global market.

**Results:** According to our data, among subjects not involved in making digital therapeutics products, the main reason for not being involved was the lack of experts (73.9%) and difficulty in licensing (73.9%). Responses concerning the priority area in need of national support were R&D funding (43.2%), and the next was licensing guidance and simplifying regulations (24.3%). Possible difficulties of overseas market expansion were the unfamiliarity in digital therapeutics technology verification and licensing structures of foreign countries (73%), and concerns regarding the level of recognition of clinical trials and technology in Korea from overseas (70.3%). Overall, respondents were hesitant in starting a related business due to the lack of government support and the complexity of the regulation process. Moreover, concerns about global market entry were similar. Being unfamiliar with the novel process and worrying about the achievement despite existing challenges were the biggest drawback.

**Conclusion:** For the digital therapeutics industry to evolve domestically and internationally, government support and guidance are essential.

**Key Words:** Digital therapeutics, health policy, government support

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## INTRODUCTION

Digital therapeutics is an innovative way of treating patients, established with the development of information technology.[1,2] Along with the development of information and communications technology, artificial intelligence (AI) and Internet of things were created and have deeply affected the daily lives of people worldwide.[3] The medical field also started applying this innovative technology by utilizing big data or AI technology to create personally customized healthcare services. Digital therapeutics support disease diagnosis, patient surveillance, and data backup for doctors in making major decisions regarding patient treatment.

Amongst many types of digital therapeutics media, software as a medical device is more profitable than developing a new drug.[4,5] It is cheaper, faster, and suitable for treating and caring for chronic diseases, which is an important social task in an aging society like Korea. Moreover, digital therapeutics can be helpful for patients who have hard time visiting hospitals due to sociodemographic or other reasons.[6] In particular, during the coronavirus disease of 2019 (COVID-19) pandemic, these types of treatment can help patients maintain their medical care.[7] Telemedicine was temporarily allowed in Korea as a result of the situation brought on by COVID-19.[8] However, according to a previous study, it was operated inefficiently due to the lack of definite guidelines.[8] Sufficient support and functional systems could make telemedicine work in a productive way for both patients and healthcare providers. Similarly, digital therapeutics is also a reliable option for patients with chronic disorders, who need to maintain treatment; however, the industry also faces a lack of guidance and structure yet.

According to a previous report, the global digital health industry was valued at $79 billion in 2015 and $96 billion in 2016, and is expected to reach about $206 billion in year 2021. The United States Food and Drug Administration (FDA) has announced "Digital Health Innovation Action Plan" in 2017 that the regulatory authorities would streamline the licensing process of healthcare products from companies that were given the "pre-cert" qualification. Pre-cert is a credentials for companies that meet the criteria for appropriate qualifications of healthcare product manufacturing company. Japan has legally allowed using telemedicine since 2015, and IT companies of Japan, including PORT medical, OPTIM, MRT started to provide the service from 2016. Digital healthcare market in Korea was valued at 2.6 trillion won in 2013, and has increasing growth rate of more than 10% each year, and expected to value in 14 trillion won in 2021. Domestic healthcare products are experiencing difficulties in their use for medical purposes due to regulations such as prohibition of telemedicine and restrictions on direct to consumer genetic test items, which is directly requested by consumers without going through medical institutions. Not a single Korean company of digital healthcare was included in the top 100 startups established since 2014, and 63 of the top 100 global digital healthcare startups were restricted from doing business in Korea due to regulations.[9,10]

Despite various business attempts in the industry, it would not be easy for companies to grow without government support, in terms of both finance and policy. In this study, we surveyed 37 individuals representing companies engaging in the digital health business in Korea. The questions inquired about exact resources that would help hands-on workers in the field, and what it takes to enter the global digital therapeutics market. Our data may provide a helpful support for constructing policies concerning the digital therapeutics industry and global market entry.

## MATERIALS AND METHODS

### Data and participants

Data used in this study were collected from members of the Korea Digital Health Industry Association (KODHIA) through a survey based on the present state of development in digital therapeutics and required supporting resources for commercialization. The survey was administered online for a week, from November 12 to 16, 2020. The survey aimed to collect data regarding the basic needs for the digital therapeutics business in Korea to expand globally.

### Survey questions

The survey included 16 major questions, 6 about the present state of development in digital therapeutics and 10 about the nationally required support for its commercialization. A total of 31 sub-questions were asked. Participants who answered "Yes" for "plan to develop or go on sale of digital therapeutics product" were to answer additional questions regarding the following: field area of the product, stage of the development, the time point of establishment, and motivation. Those who answered "No" to "plan to develop or go on sale of digital therapeutics product" were asked to answer why not.

A few questions were not included in the analysis, such as those colliding with other items. For example, if participants answered "mental health area" in the question asking about the field area of the product, and answered "chronic disease area–designing stage" and "mental health area–contents build up stage," then the "chronic disease area" part was deleted, as it would not correspond to the preceding question concerning field area of the product. Moreover, the participants were asked to score the likelihood of overseas market expansion of digital therapeutics technology on a scale of 0 to 10. A score of 10 corresponded with "most likely to expand" and 0 with "very difficult to enter the global market." The sub-questions asked why they could or could not enter the global market, about the target countries of expansion, and the national support required to succeed. Moreover, the necessity and urgency of government support were evaluated on a scale of 0 to 10 (0 being unnecessary, and 10 being essential). The necessity and urgency

of building a post-industry infrastructure for digital therapeutics technology, market-led development of digital therapeutics technology, support for digital therapeutics technology for deprived population, funding for the existing industry-linked and converged digital therapeutics technology, incubation of early-developed digital therapeutics technology, and establishing a global strategy were investigated. Finally, participants provided detailed responses for their opinions regarding the entry of digital therapeutics to the global market (Supplementary Table 1, only online).

## RESULTS

### Present state of development in digital therapeutics

*Plan to develop or go on sale with a digital therapeutics product*

Out of 37 respondents, 14 companies (37.8%) answered "Yes" and 23 companies (62.2%) responded with "No" to the question asking whether they plan to develop or go on sale with a digital therapeutics product. More than half of the enterprises did not plan to develop or sell a digital therapeutics product.

Among 14 of those who planned to develop or sell a digital therapeutics product, there were 23 field areas that were being developed. The field of mental health was the most popular at 43.5%, and the study area of "age-specific population groups" was second highest at 21.7%. Chronic disease was at 17.4%, and physical activity and related pain was at 4.3%. From those who chose "others," 8.7% comprised "rehabilitation of patients with respiratory disease and severe diseases including cancer" and 4.3% were "visual impairment related to brain damage," summing up to 13% (Table 1).

**Table 1.** Areas of Planned Digital Therapeutics Development*

| Area | Response |
|---|---|
| Mental health (ex. disorders related to depression, sleep, and diet) | 10 (43.5) |
| Population by age (ex. developmental disorder, ADHD, dementia, sarcopenia) | 5 (21.7) |
| Chronic disorder (ex. diabetes Mellitus, hypertension, hyperlipidemia) | 4 (17.4) |
| Pain and physical activity (ex. complex regional pain syndrome, hernia of intervertebral discs, muscle pain) | 1 (4.3) |
| Etc. (respiratory disease, cancer, rehabilitation, brain damage related visual impairment) | 3 (13.0) |
| Total | 23 (100.0) |

ADHD, attention deficit/hyperactivity disorder.
Data are presented as n (%).
*Multiple response questions.

*Stage of the development of a digital therapeutics product*

For the 14 respondents planning to develop a digital therapeutics product or enter the market, a question about the stage of product development was asked; the total number of responses was 23. Participants could provide multiple responses if applicable. Minimum operation stage was 26.1%, the highest; usability test and designing were 21.7% and 17.3%, respectively. Moreover, content build-up and clinical trial were both 13%, followed by the pre-market approval stage at 8.7%. No one reported being in the market-available stage (Table 2).

*Time point of establishment and motivation*

This part of the survey also concerned 14 of the respondents planning to develop or sell digital therapeutics products. From the reference point of November 2020, 3 years ago was the highest as the time point of establishing a product (42.9%). One to 3 years ago was 35.7%, and 1 year ago was 21.4%. Motivation-wise, we asked participants to answer in multiple responses if applicable. There were 21 answers collected from 14 respondents. The company-led top-down system was 64.3%, government-led and R&D contract was also 64.3%. On the other hand, the clinical expert-led request was comparatively low at 21.4%.

*Reasons not being involved in the digital therapeutics industry*

Regarding the 23 participants who were not planning to develop or enter the market with digital therapeutics products, the reasons for not being involved in the industry were investigated in the survey. Participants could have multiple responses if applicable, resulting in 64 answers. The most common reasons included the lack of experts (73.9%) and difficulty in licensing (73.9%). Premature commerce was at 60.9%, and the ambiguity of the definition of the industry at 43.5%. Too much expense consumed for development (17.4%) and being incredulous about the industry (8.7%) also occupied small parts of the responses (Fig. 1).

**Table 2.** Development Phase of Digital Therapeutics Technology by Sector

| | Design | Contents development | Minimum drive development | Usability test (safety) | Clinical trials (validity) | Preparing for commercial authorization | Commercialization | Total, n (%) |
|---|---|---|---|---|---|---|---|---|
| Mental health | 2 | 2 | 4 | 1 | 1 | - | - | 10 (43.5) |
| Chronic disease | - | 1 | 2 | 2 | - | - | - | 5 (21.7) |
| Population study | 1 | - | - | 1 | 1 | 1 | - | 4 (17.4) |
| Pain | 1 | - | - | - | - | - | - | 1 (4.3) |
| Etc. | - | - | - | 1 | 1 | 1 | - | 3 (13.0) |
| Total, n (%) | 4 (17.3) | 3 (13.0) | 6 (26.1) | 5 (21.7) | 3 (13.0) | 2 (8.7) | 0 (0.0) | 23 (100.0) |


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## Responses concerning government support in the industry

*Priority area in need of national support*

Eight options were given to the respondents to grade ranking for the most important three items as the leading area in need of governmental support. As a result, for the first ranking, R&D funding was 43.2%, followed by licensing guidance and simplifying regulations at 24.3%. The consortium of industrial-academic training, data integration platform technology development system, and inter-ministerial cooperation and pilot project implementation tied at third, with 8.1% each. In the secondary ranking, licensing guidance and simplifying regulations had 33.3% of the votes, which was the highest, and establishing and supporting clinical trial cohorts had 19.4% of the votes. Regarding the third ranking, four items tied with value of 16.2% (R&D funding, data integration platform technology development system, inter-ministerial cooperation and pilot project implementation, and establishing and supporting clinical trial cohorts). The item with the highest percentage by summing up all rankings was licensing guidance and simplifying regulations, reaching 23.6%; R&D funding was in second place by a close gap of 22.7%, and establishing and supporting clinical trial cohorts in third with 12.7% (Table 3).

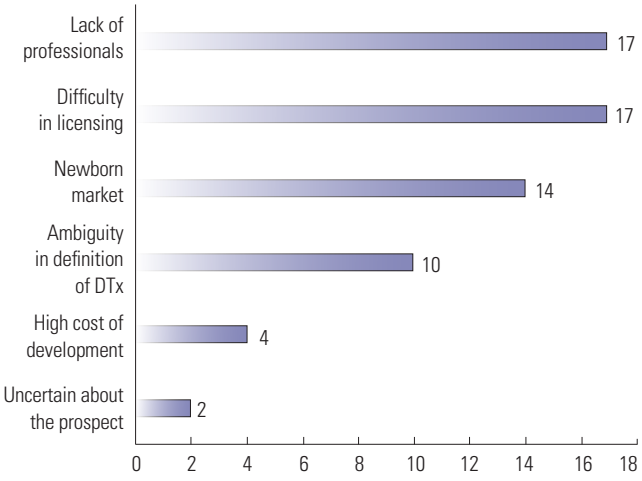


**Fig. 1.** Reasons for not being involved in DTx industry (n=64, multiple response questions). DTx, digital therapeutics.

*Estimated time and cost to develop digital therapeutics technology*

Regarding the estimated time to develop technology for digital therapeutics, more than half of the respondents responded with 3 to 5 years; 27% said 1 to 3 years, 8% said more than 5 years, and 3% said less than 1 year (Fig. 2).

As for the costs, 35% of the respondents said that more than 500 million won to less than 1 billion won would be needed for digital therapeutics technology development. Subsequently, 30% answered more than 1 billion won to less than 1.5 billion, and 24% answered more than 1.5 billion to less than 2 billion won. Comparatively, less than 5 million won (3%) and more than 2 billion won (8%) were low in percentage (Fig. 2).

*Possibility of overseas market expansion of digital therapeutics technology*

As previously stated in the methods section, the possibility of overseas market expansion of digital therapeutics technology was examined. As a result, on a scale of 0 to 10, 8 and 9 points had the highest rate of answers with 24.3%, and the prospect was positively evaluated. Dividing the 0 to 10 scale in a range of 3 points, scores 7 to 10 had 62.2%, meaning more than half the respondents supported the global expansion of digital therapeutics technology. Questions regarding the possible reasons for success of overseas market expansion produced 104 responses. The universality of digital therapeutics technology functional mechanism had the highest rate of 64.9%, followed by taking an initiating role in the global entry of digital therapeutics with 62.2%, and the universality of digital therapeutics technology verification methods had 59.5%. On the contrary, reasons regarding the difficulty of overseas market expansion were also collected (n=106). Unfamiliarity with digital therapeutics technology verification and licensing structures had the highest response rate of 73%. Recognition of clinical trial and technological level in Korea from overseas had the second highest response rate of 70.3%, followed by the lack of stakeholder networks to create business models at 54.1% (Fig. 3). A total of 75 respondents answered the question regarding the

**Table 3.** Priority of National Support Needs*

| | 1st ranking | 2nd ranking | 3rd ranking | Total, n (%) |
|---|---|---|---|---|
| R&D support | 16 | 3 | 6 | 25 (22.7) |
| Simplifying regulations and provide guidance regarding licensing | 9 | 12 | 5 | 26 (23.6) |
| Composition of the consortium | 3 | 4 | 3 | 10 (9.1) |
| Data integration platform technology development | 3 | 3 | 6 | 12 (10.9) |
| Inter-ministerial cooperation and pilot project implementation | 3 | 2 | 6 | 11 (10.0) |
| International licensing and mutual recognition and education | 2 | 3 | 2 | 7 (6.4) |
| Establishment and support of clinical trial test cohorts | 1 | 7 | 6 | 14 (12.7) |
| Training of experts in the field | 0 | 2 | 3 | 5 (4.5) |
| Total | 37 | 36 | 37 | 110 (100.0) |

*Multiple response questions.

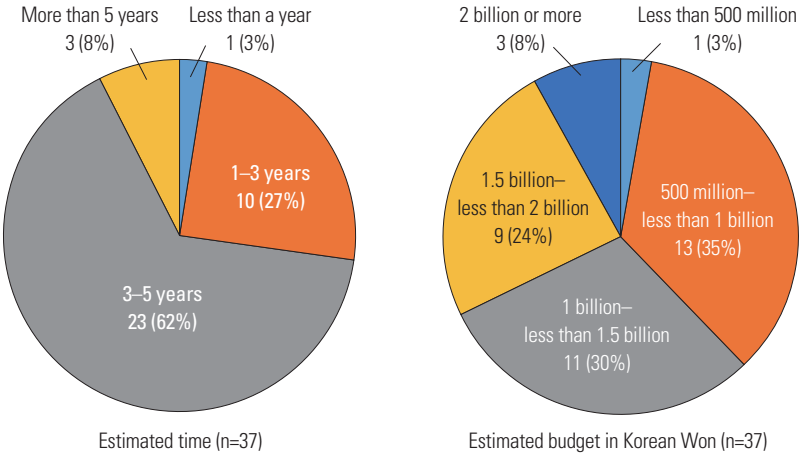


**Fig. 2.** Estimated time and budget for digital treatment technology development.

target country of expansion, with the following results: United States 91.9%, Germany 35.1%, and England 32.4%. The next highest were Japan and China, comprising 18.9% and 16.2% of the responses, respectively.

*Government funding strategies in the global extension of the Korean digital therapeutics industry*

Among the 112 answers collected, support procedures for simplifying licensing between countries through a global network between regulators cover the most responses (70.3%). Support for overseas clinical research and trial was at 64.9%, and simplifying entry into the digital therapeutics market through deregulation (tax and legal issues, etc.) was 37.8%. Regarding the necessity and urgency of government support, building a post-industry infrastructure for digital therapeutics technology had the highest score in the necessity part of the from scale 0 to 10, with a mean score of 7.59. The market-led development of digital Therapeutics technology and support for digital therapeutics technology for the deprived population followed with mean scores of 7.22 and 6.97, respectively. For urgency, among five choices, first and second place had the same tendency as the necessity; building a post-industry infrastructure for digital therapeutics technology had a mean score of 6.92, and market-led development of digital therapeutics technology had 6.76. The third highest in the urgency part was the incubation of early-developed digital therapeutics technology, with a mean of 6.70.

Descriptive opinion regarding the Korean digital therapeutics technology's entry into the global market was collected through the survey. Among the 17 responses, several new approaches were suggested, different from the answer choices given in the survey questions. Measuring the medical price, providing information about the global market, and easy access to data were aspects that needed to be addressed according to the study participants.

## DISCUSSION

This survey investigated the market status, developmental environment, and necessary national support measures from the perspective of companies that engage in the industry of digital healthcare, and the participants were members of the KODHIA. The study aimed to assemble baseline data for research on preparing strategies for entering the global digital therapeutics market and reinforcement of the market in Korea.

There is a need to improve data framework and legal and institutional procedures through a strategy to build post-industry infrastructure for the growth of digital therapeutics technology. According to data, only a minority of the respondents were uncertain about the industry prospects, and the reason for being unwilling to develop digital therapeutics technology was that the structure of licensing is unaccustomed and new to developers. Moreover, companies are struggling with licensing and regulation of digital therapeutics technologies and appear to need better support for legal and institutional procedures. Digital therapeutics differ from other wellness wearable devices or apps, requiring certain scientific or clinical evidence before being prescribed or recommended by a doctor.[11] Since evidence is required, regulations upon defining and managing digital therapeutics are mandatory for success in this field. Nevertheless, since it is hard for developers to handle legal controls, the government should support entrepreneurs to get the first grip of that business sector. Digital therapeutics also need to go through clinical trials, just like the development process of any new drug. This may help verify the validity and safety of the treatment for patients in need. Moreover, since digital therapeutics contain personal data, transmitting and saving the medical records of an individual, a security guideline should be established and notified.[12]

In order to preempt the global digital therapeutics market, the development of major digital therapeutics technologies, such as those for mental health, chronic diseases, and national R&D, must be supported. In particular, the Korean industry


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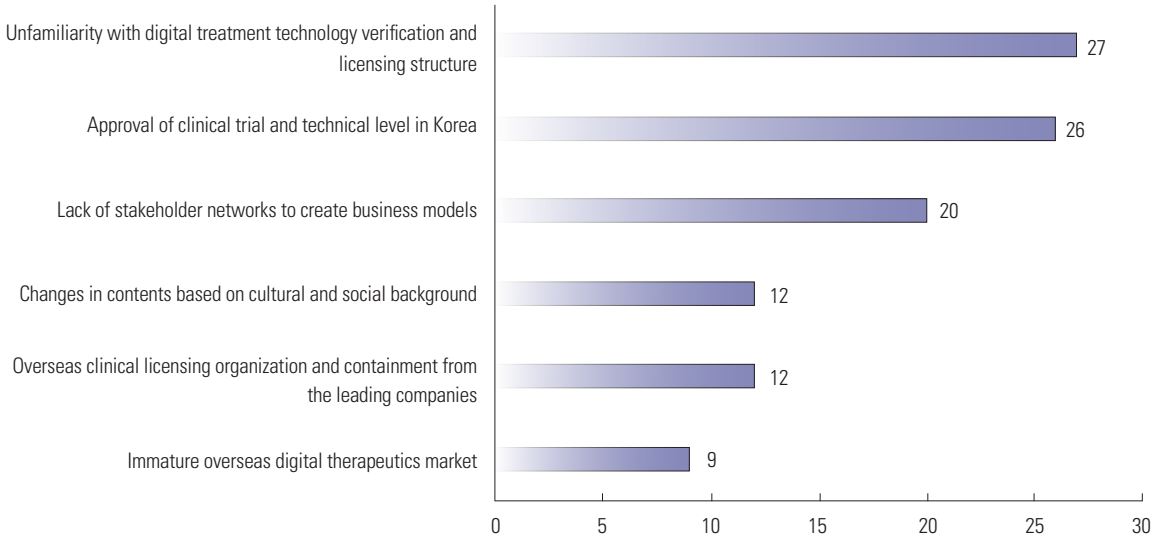


**Fig. 3.** Possible difficulties against the global market entry of digital therapeutics technology developed in Korea (n=106, multiple response questions).

is actively developing digital therapeutics technologies in the mental healthcare sector. Strategic support should be provided at the government level to acquire a leading role in the global market, including actively developing those areas in Korea. Since areas related to chronic diseases or age-specific population-based research are being developed, a government-level support plan should be considered. As reported from the data, government support is a necessary measure for digital therapeutics technology development, and is considered the most substantial motivator for digital healthcare companies.

It is crucial to establish direct and indirect support processes, such as training human infrastructure, while reinforcing the existing digital therapeutics technology. In favor of easier access to the global market, a study on the major regulations of the United States and Europe should be implemented, as well as clinical and economic evaluation guidelines for digital therapy techniques by each country.[13-16] For instance, reSET (Pear Therapeutics Inc., Boston, MA, USA), was the first digital therapeutics approved by the FDA in 2017 for the treatment of substance use addiction, through randomized controlled clinical trials.[1] The treatment process starts with prescription by a doctor. The patient follows the app instructions and provides real-time data about triggering factors and cravings at the moment, regardless of time and place. Then, using the algorithm programmed in the app, patients can receive an online consultation of their immediate situation. This has similar effects as an outpatient visit; not only does it lower the medical expenses for patients, but also does it provide data for the doctors to follow up with the patients' daily lives.[17,18] Following reSET, there are few other digital therapeutics products in the market already, and many more have been earning FDA approval consistently since 2017.[19-22] According to a previous study, in the United States, financial investment to promote the growth of a new business model in this field is actively occurring, which has tripled from about $1.5 billion in 2012 to $6 billion in 2017. There are about 320,000 health management mobile applications in the mobile app store, and this was double the number from 2015. Moreover, the recent COVID-19 pandemic has accelerated these investments, reaching $16 billion in 2020, which was twice the amount from 2019.[23]

In order to solve the complexity of government regulations, progressive strategies should be suggested from the professionals, and specific plans should be claimed in scholarly journals. Moreover, the implementation of pilot projects sponsored by government sectors for the development of innovative technology should be done actively. Economic evaluation research on digital therapeutics should also be boosted to provide evidence on the spread and development of the digital therapeutics industry in Korea.

This study had a few limitations. First, despite the description of digital therapeutics and digital treatment technologies provided in the survey, the interpretation of the definition of digital treatment technology may differ for each respondent. Second, this survey did not inquire any personal information and general characteristics about the participants, including no sociodemographic and socioeconomic features. Therefore, related bias may have occurred. Also, response bias and non-response bias may exist, as the responders may have provided inaccurate or false answers. Non-responders from a sample may differ in a meaningful way to responders. Moreover, selection bias might exist, as no process of randomization was processed when acquiring the sample. Another limitation is the small sample size of the study. However, this survey was still meaningful, as it gathered opinions of actual staff engaged in the business about the resources needed and the order of priority in implementing the global market entry of Korean digital therapeutics technology. Based on the survey results, further research with more detailed survey questions in a wide range of areas should be per-

formed in the future.

From the survey results, we can assume that many people in the field are hesitant about starting a business in digital therapeutics, as it is unfamiliar to them. Government support and guidance are essential for the digital therapeutics industry to evolve both domestically and internationally. We believe that this survey would assist the government to incubate new markets for digital healthcare.

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