

July 2024

# Navigating the Landscape of Digital Health

## South Korea



EWHA WOMANS  
UNIVERSITY



THE ACCESS AND  
DELIVERY PARTNERSHIP



**HTAP**  
Health Intervention and Technology Assessment Program

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**Acknowledgements**- The author wishes to acknowledge inputs and contributions from Saudamini Dabak for reviewing the report. Further acknowledgements are extended to Dr. Pritaporn Kingkaew, Sarin KC, Dimple Butani from HITAP for their valuable inputs and feedback on concept, design and scope of the report. Lastly, the author thanks Panchanok Muenkaew from HITAP for supporting in formatting of the report.

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**Disclaimer** – This report is a product of a study lead by HITAP to understand the digital health landscape in Australia, England, India, Indonesia, Singapore, South Korea, and Thailand. The study was supported by the Access and Delivery Partners (ADP) and the Health System Research Institute (HSRI) on behalf of Ministry of Public Health Thailand (MoPH). The views expressed in this document are solely those of the authors and do not necessarily reflect the views of their affiliated or the partner organisations. In particular, the findings, interpretations, and conclusions expressed in this work neither necessarily reflect the views of funder organisations the HSRI, Thai MoPH and ADP nor do they guarantee the accuracy of the data included in this work. The information presented in the report reflects the landscape of Digital Health in South Korea as of 2022.

More information on this project is available here: <https://www.hitap.net/en/research/183722>.

## Disclosure

No conditions or limitations on authors' independence in research including data collection, analysis, reporting and resultant conclusions, recommendations, and publications are attached to any funding received.

Cover image designed by Pattama Nualpenyai, HITAP

## EXECUTIVE SUMMARY

Digital health in Korea encompasses a wide range of technologies and services yet lacks a clear legal definition. The Korea Institute for Industrial Economics & Trade (KIET) classifies digital health into hardware, software, and service categories, reflecting the diverse landscape of telehealth, mobile health, and smart healthcare. The Korean government, under the Korean New Deal Master Plan 2.0, has prioritized digital health to address economic challenges exacerbated by COVID-19. Through initiatives like the Digital New Deal, amendments to the Personal Information Protection Act, and investments in smart healthcare infrastructure, Korea aims to harness digital innovation for societal benefit.

Though recent statistics on the domestic digital health market are lacking, estimates suggest significant growth potential. Major ICT companies like Samsung, LG, Naver, and Kakao are investing in telemedicine and AI-based healthcare solutions, while startups like LifeSemantics and MEDIHERE offer digital therapeutics and telemedicine platforms. Regulatory oversight is provided by agencies like the Ministry of Health and Welfare (MOHW) and the Ministry of Food and Drug Safety (MFDS), which enforce laws and evaluate health technologies' clinical effectiveness. However, challenges persist in regulatory clarity for wearables, mobile medical applications, and telehealth services. Digital literacy in Korea is improving, yet gaps remain, particularly among vulnerable groups like the elderly and low-income individuals. Efforts to bridge this divide are underway, with initiatives like the National Information Society Agency's digital data gap survey. The Health Technology Assessment (HTA) process for digital health technologies involves rigorous evaluation for insurance coverage, ensuring safety, effectiveness, and cost-efficiency. Guidelines for AI medical imaging and 3D printing technologies exemplify this process, though challenges exist in standardizing evaluations.

Despite challenges such as regulatory hurdles and a diagnosis-centric healthcare system, Korea possesses strengths like advanced ICT infrastructure and government initiatives like the Korean New Deal. Opportunities abound for digital health innovation to address societal needs and propel Korea toward a more equitable and efficient healthcare system.

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# 1. INTRODUCTION

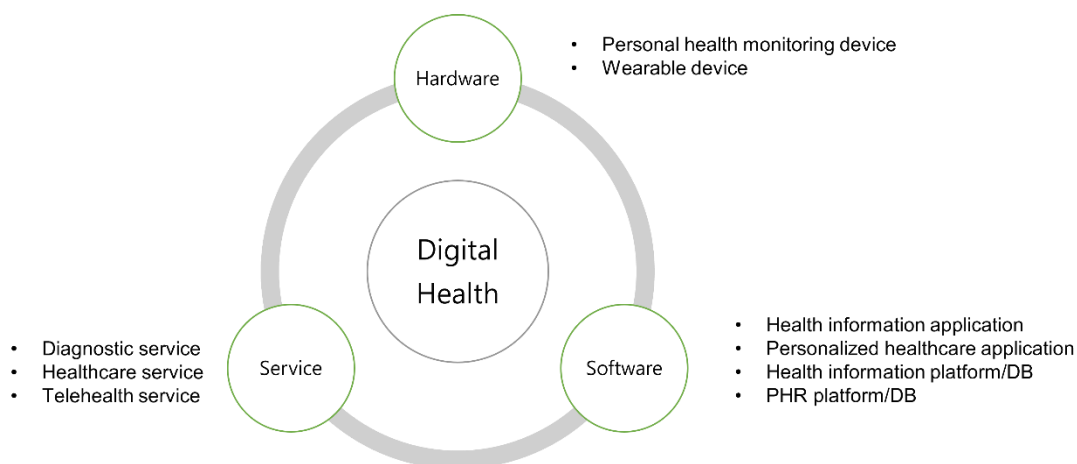
## 1.1 Definition and classification of digital health in Korea

In Korea, the legal and regulatory system does not provide a clear definition of digital health. Terms used for digital health vary and include telehealth, telemedicine, telemonitoring, electronic health (e-health), mobile health (m-health), ubiquitous health (u-health), smart healthcare, etc. according to the development of technology and its specific field.

Even though there is no clear definition, many regard digital health as a broad term. According to Korean Health Industry Development Institute (KHIDI), digital health is a broad concept that embraces smart health and mobile health which can provide personalized healthcare and medical service. In addition, the Korea Institute of Science & Technology Evaluation and Planning (KISTEP) refers to digital healthcare as a convergence of the medical field and ICT and considers digital health as a broad concept (1) including E-health, U-health, mobile healthcare, smart healthcare etc.

On the other hand, Korea Institute for Industrial Economics & Trade (KIET) classifies digital health into three types according to the form as shown in the following Figure 1: hardware, software, and service. Personal health monitoring devices and wearable devices are classified as hardware, health information application, personalized healthcare application, health information platform/DB, and personalized health record platform are classified as software, and lastly, diagnosis, healthcare, and telehealth are classified as service.

**Figure 1 Classification of digital health.**



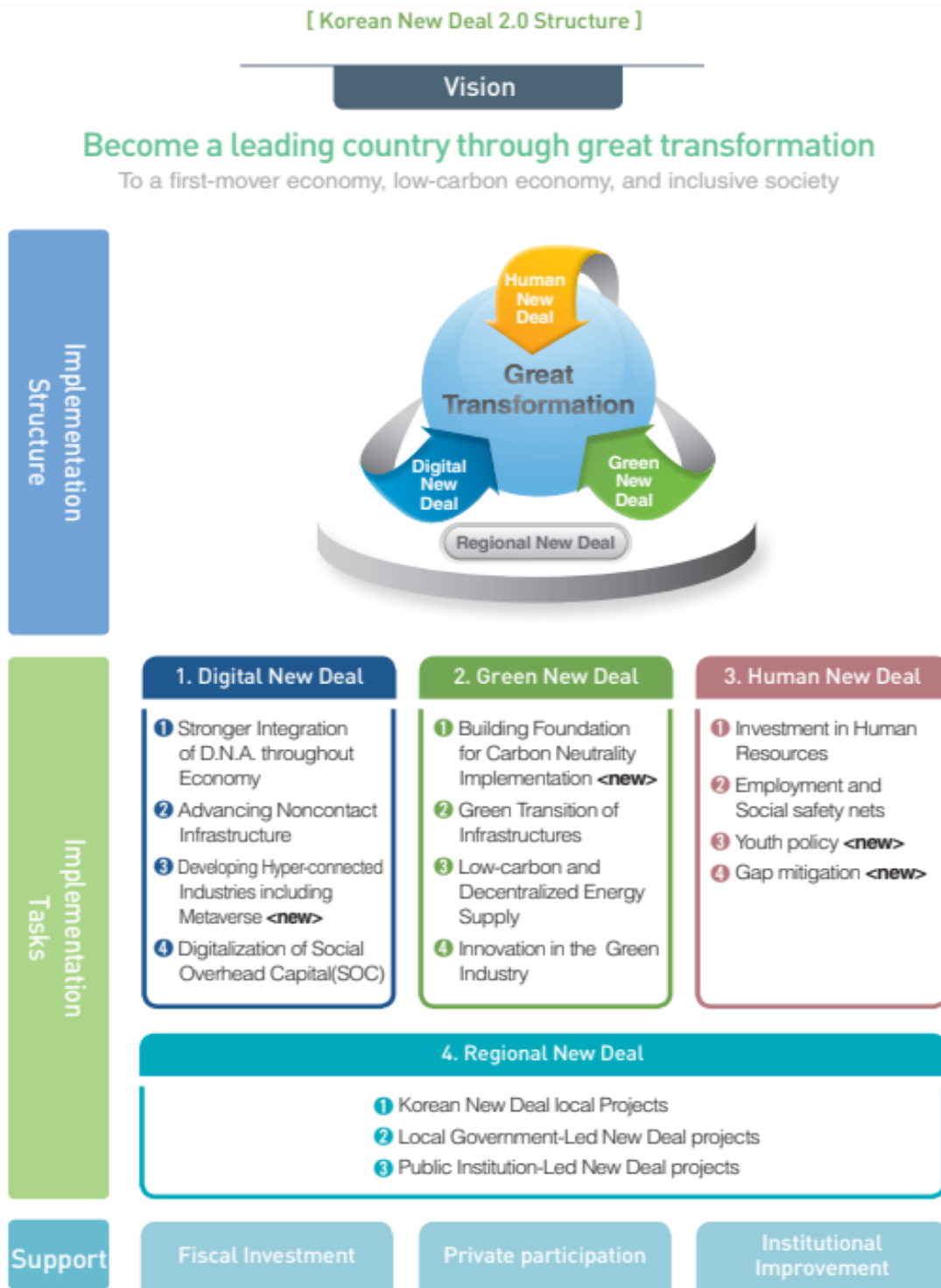
Source 1: Author's analysis.

## 1.2 Current state of the digital health industry in Korea

The Korean government introduced the Korean New Deal Master Plan 2.0 (July 2021) to overcome the economic crisis caused by COVID-19 and to preemptively respond to changes in economic and social structures. Among four implementation tasks, specific plans for digital health are mentioned in the 'Digital New Deal'.

In the 'Digital New Deal', the foundation for the deployment of "My Data" across all industries and using My Data in the public sector, healthcare, and other areas has been established through the amendment of the Personal Information Protection Act. In addition, the government will support pseudonymous information processing to activate its use of it. The Digital New Deal also aims to build smart health/care infrastructure such as operating Doctor Answer clinics and deploying smart emergency care services (2).

Figure 2 Korean New Deal 2.0 Structure



Source 2: Ministry of Strategy and Finance. (2021, September 30). Korean New Deal. Ministry of Strategy and Finance. Retrieved [20 June 2024]

## **Domestic digital health market trends**

There are no recent authorized statistics on the domestic digital health market yet. However, KHIDI estimated the market size of digital health in Korea to be 1.7 trillion won (approximately USD 1.3 billion) in 2010, and Hyundai Research Institute (HRI) predicted it to become 14 trillion won (approximately USD 11 billion) 2020, which is a very optimistic speculation considering limitations and environment surrounding Korea's digital health industry (3).

Even though Korea has enough foundation to develop a digital health industry -superb medical human resources, outstanding medical infrastructure, and remarkable information and digital infrastructure, its competitiveness compared to other leading countries like USA and China is quite weak because of convenient access to medical facilities, several relevant regulations, and diagnosis/treatment-oriented payment system. Regulations on medical big data, telemedicine, and direct-to-consumer DNA test are the typical regulations on digital health, and 75% of global digital health start-ups are experiencing difficulties in launching businesses in Korea because of these several regulations.

The following examples are typical companies that are running businesses related to digital health in Korea. In addition to the companies presented in this report, there are many more domestic companies in the digital health business.



**Table 1 Example of typical companies that are running businesses related to digital health in Korea.**

No.	Company name	Digital health businesses
<b>ICT companies</b>		
1	Samsung Electronics	- Samsung Health Monitor - Investment to a start-up Ada Health developing telemedicine service based on AI
2	LG Electronics	- A telemedicine solution based on a cloud service
3	Naver	- Clova Care Call, an AI service to manage daily lives of one-person households - Registration of a trademark 'Naver Care'
4	Kakao	- Establishment of a branch corporate 'Kakao healthcare'
5	SK Telecom	- A business for AI-based early diagnosis and progressive behavioral treatment for the developmentally disabled - Agreement with GE healthcare to establish a digital infrastructure for domestic digital healthcare - Establishment of a digital healthcare-specialized corporation 'Invites Healthcare'
6	KT	- A business agreement with Vietnam with Hanoi Medical University for a telemedicine service to manage chronic diseases
<b>Telemedicine and medical information technology companies</b>		
1	LifeSemantics	- Life Record, the first digital health technology platform based on personal health record (PHR) - Redpill Breath, a rehabilitation program to breathe - Redpill Care, a digital therapeutic to manage prognosis of cancer - Doctor Call, a telemedicine solution - H.AI, a predictive service estimating the possibility of risk
2	MEDIHERE	- DoctorHere, telemedicine membership service - An agreement with Doctor Diary providing a platform to manage diabetes to link its telemedicine platform with it
3	DoctorNow	- A telemedicine and medication delivery service
4	ezCaretech	- A technology to guarantee the order of production and handling messages in EMR
5	Lemon Healthcare	- An application service to issue mobile certificates and to conveniently claim loss insurances with Seoul National University Hospital

## 1) ICT companies

### ① Samsung Electronics

Samsung Electronics is one of the biggest conglomerates in Korea manufacturing semiconductors, smartphones, and other numerous home appliances.

'Samsung Health Monitor' is a health monitoring application that can measure and record users' blood pressure and electrocardiogram through wearable devices. Samsung Electronics expanded this application service to 31 new countries in February 2021.

In addition, in May 2021 it made a huge investment in a start-up Ada Health which developed a telemedicine service based on artificial intelligence with Bayer, a German pharmaceutical company. Ada Health has developed an application to diagnose patients' symptoms using AI. When users input their symptoms, the AI asks some relevant questions and suggests a reason for the symptoms and what to do to solve the problem based on the gathered information. The company revealed that it aims to invest in not only expanding its business in the USA but also in improving AI algorithms, broadening the foundation of medical information, and extending its services in 10 languages.

### ② LG Electronics

LG Electronics is another major company manufacturing home appliances in Korea. In August 2021, the company released a telemedicine solution based on a cloud service developed with a professional domestic digital health company. It is based on a video conference platform, so it can be utilized not only for patients' telemedicine but also for large-scale conferences. And it can be easily linked to each hospital's system that established respective electronic medical records (EMR) or hospital information system (HIS). Also, it enables people to access the solution without physical restrictions as it is a cloud service.

③ Naver

Naver provides one of the most representative search engines 'Naver' in Korea, and it is developing several new ICT-based services and businesses. A consortium including Naver provides an AI service to manage the daily lives of one-person households, Clova Care Call, which helps reduce the depression or loneliness of the middle-aged and suggests diet, outdoor activities, and physical exercises. And the company registered a trademark 'Naver Care', which means that the company is planning to expand its telemedicine business. In addition, they have a plan to introduce AI technologies that consult patients before visiting their in-house hospital, which enables estimating approximate reasons for symptoms and suggesting possible diseases and preventive guidelines for the future.

④ Kakao

KaKao is another conglomerate that provides a search engine, free text messaging service, and numerous other mobile services. It established a branch corporate 'Kakao Healthcare' to run several businesses – comprehensive management and maintenance of information systems, a healthcare service, an AI-based medical solution service, etc. For this plan, the company is currently recruiting developers and engineers to build the appropriate foundation.

⑤ SK Telecom

SK Telecom is the biggest telecom company in Korea. Firstly, in December 2021, the company agreed with Seoul National University Hospital to run a business for 'AI-based early diagnosis and progressive behavioural treatment for the developmentally disabled'. This business has three big goals for early diagnosis and treatment of developmental disability: 1) the development of an application for caregivers to collect and manage data related to developmental disability, 2) the development of AI solutions and data collection, and 3) the development of digital therapeutics. Secondly, it also agreed with GE Healthcare in September 2021 to establish a digital

infrastructure for domestic digital healthcare. They have a plan to expand 5 G-based services and to provide mobile edge computing (MEC) and cloud service to raise the efficiency of medical facilities and provide better service and experience to patients. Thirdly, it established a digital healthcare-specialized corporation, 'Invites Healthcare' with partners who have abundant experience in healthcare businesses. It aims to run diverse businesses to help health promotion and innovation of medical institutes through ICT technologies in the domestic and global markets.

\*MEC (mobile edge computing): A computing method that provides ultra-low latency by locating a server close to users who want to use mobile communication services and processing data right at the site where data is collected, and efficiently manages processing and storage of exceptionally large data.

#### ⑥ KT

KT is the second-biggest telecom company in Korea, and it is also expanding its businesses in digital technology fields. The company signed a business agreement in Vietnam with Hanoi Medical University for a telemedicine service to manage chronic diseases in April 2022. This telemedicine service provides a self-care guide including the management of medication and physical exercises for patients with chronic diseases like diabetes and high blood pressure. Through this cooperation, it is planning to launch a pilot service of a telemedicine platform in Vietnam, and it is considering a plan not only to establish a Vietnamese branch but also to build an independent digital healthcare corporation eventually.

## 2) Telemedicine and medical information technology companies

### ① LifeSemantics

LifeSemantics was established in September 2012 and is running businesses in various digital health sectors. The company is developing and providing services like telemedicine, digital therapeutics, and MyData to prevent and manage diseases and reduce health expenditures. Their key technology is 'Life Record', which is the first

digital health technology platform based on personal health records (PHR) in Korea. For example, 'Redpill Breath' is a rehabilitation program to breathe, and 'Redpill Care' is a digital therapeutic to manage the prognosis of cancer. Also, there is a telemedicine solution 'Doctor Call' and a predictive service 'H.AI' that estimates the possibility of risk based on health screening data and supports sales of insurance.

## ② MEDIHERE

MEDIHERE is a digital health start-up providing telemedicine membership service 'DoctorHere' to Koreans abroad who have difficulties accessing medical services. After the temporary allowance of telemedicine in Korea because of COVID-19, there were 20,000 cases of telemedicine in only six months, which proves the possibility of growth and stability of the platform. Also, they made an agreement with Doctor Diary that provides a platform to manage diabetes, to link MEDIHERE's telemedicine platform with it.

## ③ DoctorNow

DoctorNow provides a telemedicine and medication delivery service with about 900 affiliated medical institutes across the country. It was illegal to conduct telemedicine in Korea before COVID-19, but after the temporary allowance, the amount of usage is rapidly increasing. Until the 1<sup>st</sup> quarter of 2022, about 3 million people used DoctorNow's service cumulatively, and the range of users' age is also expanding from the twenties to thirties.

## ④ ezCaretech

The company invested in a technology to guarantee the order of producing and handling messages in EMR which was patented in March 2022. This technology was applied to ezCaretech's cloud-based EMR 'EDGE&NEXT', and it has been improving patients' safety and medical staff's task efficiency. Also, they revealed in February 2021 that they are planning to add nine business purposes including 'development

and provision of AI-based medical solution’ and ‘provision of PHR-based health management service’.

⑤ Lemon Healthcare

The company started an application service to issue mobile certificates and to conveniently claim loss insurance with Seoul National University Hospital in July 2021. It is expected to reduce unnecessary usage and issue of the paper and to efficiently manage payment and claiming tasks.

## 2. THE REGULATORY FRAMEWORK FOR DIGITAL HEALTH

### 2.1 Regulatory agencies and laws related to digital health.

There are five major regulatory agencies related to digital health in Korea.

**Table 2 Five major regulatory agencies related to digital health in Korea.**

No.	Institution Name	Role
1	Ministry of Health and Welfare (MOHW)	To enforce relevant laws and oversee overall relevant projects
2	Ministry of Food and Drug Safety (MFDS)	To enforce relevant laws with MOHW and establish a comprehensive plan for medical device policies
3	Health Insurance Review and Assessment (HIRA)	To evaluate health insurance coverage and decide the level of compensation
4	National Health Insurance System (NHIS)	To administer and pay insurance benefits
5	National Evidence-based healthcare Collaborating Agency (NECA)	To assess the clinical effectiveness and economic efficiency of health technologies

Firstly, the Ministry of Health and Welfare (MOHW) enforces relevant laws and oversees overall relevant projects as follows:

- The Medical Services Act

- Fostering Medical Devices Industry and Innovative Medical Devices Support Act
- The Pharmaceutical Affairs Act (PAA)
- The Medical Care Assistance Act
- The National Health Insurance Act
- The National Basic Living Security Act

Secondly, the Ministry of Food and Drug Safety (MFDS) enforces relevant laws with MOHW and establishes a comprehensive plan for medical device policies. Also, it authorizes health technologies based on their safety and effectiveness. Currently, it operates the 'Medical Device Information Support Centre. Thirdly, the Health Insurance Review and Assessment (HIRA) evaluates health insurance coverage and decides the level of compensation. It makes decisions on whether to introduce new medical devices or technologies into health insurance. Fourth, the National Health Insurance System (NHIS) administers and pays insurance benefits. It collects, manages, and maintains National Health Information data and provides them for academic and policy research. Lastly, the National Evidence-based healthcare Collaborating Agency (NECA) assesses the clinical effectiveness and economic efficiency of health technologies (1).

## **2.2 Regulatory framework by type of digital health**

### **① Hardware - health monitoring device and wearable device**

Health monitoring devices require approval from the Ministry of Food and Drug Safety, but for now, there are no regulations or policies for wearable devices. In addition, regulation refinement of telehealth and medical big data usage is required to invigorate the wearable device industry (4).

### **② Software – digital therapeutics**

In 2020, the "Fostering Medical Devices Industry and Innovative Medical Devices Support Act" was enforced and the 'Guideline on Review and Approval of Digital Therapeutics' was announced. According to the act, digital therapeutics can be regarded as innovative medical devices which have exceptional cases concerning permission and deliberation of priority review or phase-specific rapid review.

To foster digital therapeutics, the policy will be expanded henceforth. For example, through the digital new deal in Korean New Deal 2.0, implementation tasks of smart healthcare are proposed. Also, through the bio-health industry innovation strategy, supporting the validation of effectiveness and the market entrance of innovative digital healthcare devices are announced.

### ③ **Software – health information, PHR Platform**

According to the Medical Services act, a patient's Electronic Medical Record (EMR) shall be maintained at each medical institution and only the patient him/herself is allowed to inspect the medical record. However, revisions of enforcement rules and the enactment of guidelines were made. According to the revision, EMR can be kept outside of medical institutions in the facility or equipment that meets criteria such as a backup system, redundancy of new instalment of the restricted area, etc. Also, the 'Guideline of Personal Information De-identification is enacted to expand the use of medical records (5).

### ④ **Software – mobile medical application**

No regulation or policy is yet established for mobile medical applications. However, MFDS enacted the 'Guideline for Safety Management of Mobile Medical Applications' (6) which is applied to a product used for

- diagnosing, curing, alleviating, treating, or preventing a disease
- diagnosing, curing, alleviating, or correcting an injury or impairment
- testing, replacing, or transforming a structure or function.

Examples of a mobile medical applications include:

- an application that controls insulin secretion by sending signals to the insulin pump
- an application that enlarges, reduces, and requests medical images transmitted from Picture Archiving and Communication System (PACS)
- an application connected with a blood glucose meter to measure and display blood glucose levels
- an application that amplifies the sound of the heart or lungs using microphones, speakers, etc. of the mobile platform itself and uses them for diagnosis (4).



### ⑤ Service – telehealth and telemedicine

According to the "Medical Services Act" and "Pharmaceutical Affairs Act", telemedicine (between physician-patient) and remote dispensing or distributing drugs are forbidden. Telehealth (between physician-medical personnel) is legalized, however, because of a lack of infrastructure, fee system, and regulations, the utilization rate is low.

**Table 3 Summary of relevant acts for telehealth and telemedicine service**

Act		Summary
Medical Services Act	[Article 17] No person shall prepare and issue a medical certificate, postmortem examination report, or prescription to a patient	<u>Shall not</u> issue a medical certificate, postmortem examination report, or prescription by telehealth
	[Article 33] Medical personnel shall not provide medical services unless and until he/she establishes a medical institution	<u>Shall not</u> provide medical services except for the medical institution
	[Article 34] Medical personnel may provide telemedicine services to furnish medical knowledge or technology to medical personnel in a remote area by using information communication technology	<u>Shall not</u> provide medical services except for the medical institution
Pharmaceutical Affairs Act	[Article 23] pharmacists or oriental medicine pharmacists shall dispense drugs and limited at a pharmacy or a dispensary of a medical institution	<u>Shall not</u> remotely dispense drugs
	[Article 50] No pharmacy founder or drug distributor shall distribute drugs at a place, other than his or her pharmacy or shop	<u>Shall not</u> distribute drugs. by online or contactless

Several pilot projects were implemented for people who lack access to essential healthcare services. They include the military, long-term care centers, vulnerable areas, prisons, and chronic disease patients (hypertension and diabetes).

On the other hand, due to the COVID-19 outbreak, consultation and prescription via telemedicine were temporarily allowed in Korea from March 2020 (1). Except for those living in an environment with high infection risks such as young children, people with physical disabilities, or seniors aged 70 or above living without carers, COVID-19 patients received at-home treatment (self-isolation). Therefore, patients can contact the closest hospital and receive medical treatment via phone call or mobile application. After the patient receives a consultation, the doctor sends the prescription to the pharmacy through FAX or e-mail and the pharmacy prescribes medicine to the patient in person or to the family.

Moreover, from August 2019 to August 2023 (for 48 months), Gangwon Province (Chuncheon-si and Wonju-si) has been selected as a regulation-free special zone to foster digital healthcare. Six regulation exemptions as follows will be applied to telemedicine and monitoring by wearable devices.

- Diabetes, blood pressure management service based on the medical information
- Real-time influenza vaccine demand forecasting Artificial Intelligence System Using DUR
- Bio-signal monitoring healthcare service
- The bio-signal (the chronic diseases from home) monitoring service
- Smart portable X-ray diagnosis system

#### ⑥ **Service – health analytics**

In Korea, only medical institutions are allowed to provide direct-to-consumer (DTC) genetic tests. However, only when there is a request from medical institutions and the results of tests are provided to the consumer by medical institutions, non-medical institutions can perform genetic

tests exceptionally.

After the amendment of "Bioethics and Safety Act", non-medical institutions can provide 12 items of DTC and 56 items from some institutions which received quality control certification from MOHW's pilot test (1).

**Table 4 Test items that non-medical institutions can provide.**

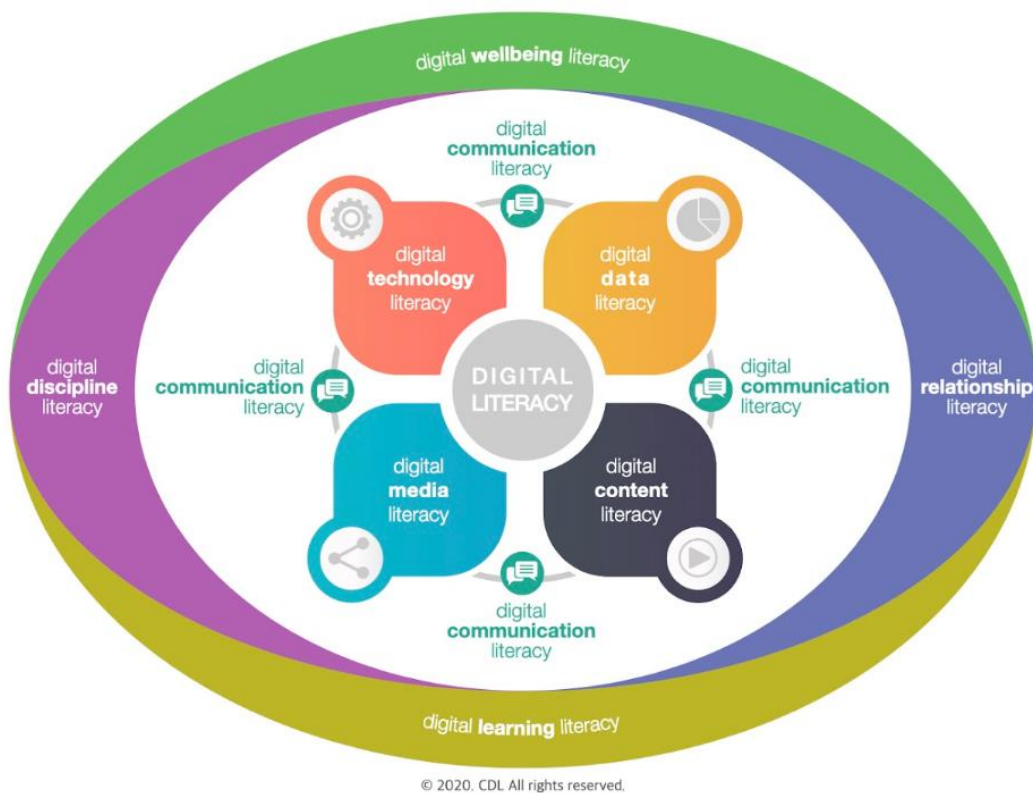
<b>Classifications</b>	<b>Items</b>
Nutrients	Vitamin C concentration, Vitamin D concentration, Coenzyme Q10 concentration, Magnesium concentration, Zinc concentration, Iron storage and concentration, Potassium concentration, Calcium concentration, Arginine concentration, Fatty acid concentration
Exercise	Muscle fitness, Muscle development ability, Grip force, Suitability for aerobic exercise, Ability for short distance running, Ability to recover after exercise, Suitability for endurance exercise, Risk of an ankle injury
Skin & Hair	Pigmentation, Hair thickness. Skin ageing, Skin elasticity, Hair loss, Freckles, Acne, Tanning after sun exposure, Skin inflammation, Stretch mark/keratin, Alopecia areata
Dietary habits	Appetite, Satiety, Sensitivity for salty·bitter·sweet taste
Personal traits	Caffeine metabolism, Alcohol metabolism, Wine preference, Alcohol dependence, Nicotine metabolism, Caffeine dependence, Morning or night person, Sleep habits/time, Alcohol flush, Insomnia, Pain sensitivity
Healthcare	Triglyceride concentration, Cholesterol, BMI, Blood pressure, Blood sugar, Susceptibility to degenerative arthritis, Motion sickness, Obesity, Uric acid, Percentage of body fat
Lineage	Ancestry

### 3. DIGITAL LITERACY IN SOUTH KOREA

#### 3.1 Definitions of digital literacy

The United Nations Educational, Scientific and Cultural Organization (UNESCO) defined digital literacy as “the ability to access, manage, understand, integrate, communicate, evaluate and create information safely and appropriately through digital technologies for employment, decent jobs and entrepreneurship” (7). And Centre for Digital Literacy (CDL), a nonprofit organization fostering digital talent in Korea defines it as “the ability to read, analyze, write, and communicate using 9 digital literacies” as the following figure.

Figure 3 Types of digital literacy by CDL (2020)



Source 3: Center for Digital Literacy. (n.d.). Digital Literacy. Retrieved [24 June 2024], from <https://sites.google.com/view/cdlorg/digital-literacy>.

#### 3.2 Current state of digital literacy in Korea (8)

The importance of digital literacy is being emphasized in the era of rapid digital transformation.

And the COVID-19 pandemic is taking a toll on not only the economically disadvantaged but also the digitally disadvantaged, further widening the digital divide (9).

In Korea, starting with understanding the reality of the information gap among the information-vulnerable class such as disabled people, the digital data gap survey is conducted every year for the public, disabled people, the low-income class, and farmers and fishermen by the National Information Society Agency (NIA). The purpose of this survey is to review the annual performance of the digital information gap bridging policy and to provide basic data necessary for checking and deriving effective policy directions in the future. In this survey, the level of digital informatization is measured by three aspects: accessibility, competency, and utilization. Accessibility is assessed by whether a respondent possesses any mobile or computer devices or can use the internet anytime and anywhere. Competency means the basic ability to use a computer and mobile devices, and utilization means the degree of quantitative and qualitative utilization of the internet through computer and mobile devices.

According to NIA's "The Report on the Digital Divide (2021)", based on the survey implemented during the period from September 2021 to December 2021 through a face-to-face interview with a structured questionnaire, compared to the general public (level of 100%), the level of digital information of the four information-vulnerable groups (the disabled, the low-income, farmers and fishermen, the elderly) was 75.4% in 2021, which is an increase of 2.7% point relative to 72.7% in 2020. By aspects, the level of accessibility, competency, and utilisation was 94.4%, 63.8%, and 77.6%, respectively. And by classes, the class that had the lowest level of digital informatization was the elderly group (69.1%), and the one that had the highest level was the low-income group (95.4%).

**Table 5 The level of digital informatization by aspects (unit: %)**

	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>
Accessibility	91.1	91.7	93.7	94.4
Competency	59.1	60.2	60.3	63.8
Utilization	67.7	68.8	74.8	77.6

Total	68.9	69.9	72.7	75.4
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**Table 6 The level of digital informatization by classes (unit: %)**

	2018	2019	2020	2021
Disabled people	74.6	75.2	81.3	81.7
The elderly	63.1	64.3	68.6	69.1
The low-income	86.8	87.8	95.1	95.4
Farmers and fishermen	69.8	70.6	77.3	78.1
Average	68.9	69.9	72.7	75.4

※The average of the four classes is a weighted average that considers the population size of each class.

Recently, a study to develop an assessment tool for eHealth literacy and to assess its reliability and validity was published in Korea. In this study, “The Korean eHealth Literacy Scale (K-eHEALS) was developed based on eHEALS, a widely used tool” to assess eHealth literacy developed in Canada by Norman and Skinner (10). And it turned out that the validity and reliability of K-eHEALS are promising. This study is significant in that it was the first attempt to translate eHEALS into Korean. However, there is no common and representative tool to measure and diagnose the level of digital literacy in Korea yet.

### 3.3 Measures to improve digital literacy in Korea.

① ‘Digital-Baeumteo’ (Digital Learning Centre)

Digital-Baeumteo is a digital competency education program run by the Ministry of Science and ICT of Korea and NIA to reduce the digital gap due to generational, regional, and economic differences. In 2021, more than 1,000 digital learning centers nationwide were operated a total of 656,000 people participated in the education program. Anyone can visit digital learning centers operated near their homes and receive free mobile and real-life-oriented digital competency education.

② ‘Digital Literacy Reinforcement Education’ run by Gyeongju-Si

This is the first specialized education course conducted by the local government in Gyeongsangbuk-do. The curriculum is divided into two classes, the basic course (50 students)

and the advanced course (45 students) and is conducted 8 times (2 hours of training per session). The educational contents are designed to cultivate basic knowledge and abilities related to the use of various digital technologies and tools (understanding the digital age, smartphone usage, SNS usage techniques, non-face-to-face distance education, YouTube usage, photo and video editing, blog in-depth education, understanding and practice of Metaverse, etc)

③ Health Plan 2030, 2021~2030 (11)

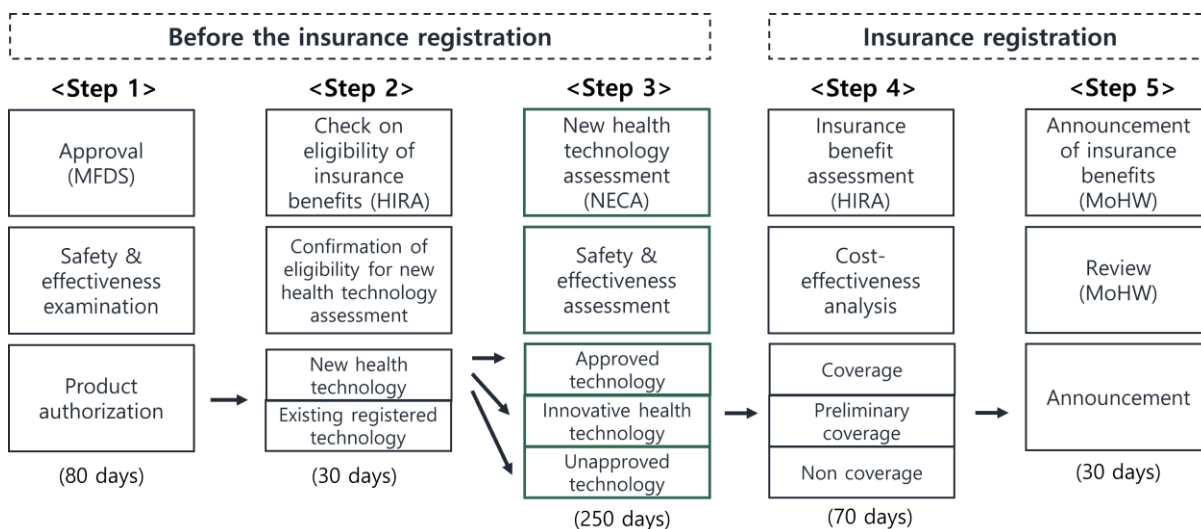
'Improving health information comprehension' and 'Application of innovative information technology' were included in the main strategies, which is a very appreciable change for the government to establish a plan to manage people's health and digital literacy.

## 4. THE HTA PROCESS AND METHODS FOR DIGITAL HEALTH TECHNOLOGIES <sup>(12, 13)</sup>

### 4.1 Procedure of national health insurance (NHI) registration for health technologies

For a new health technology to be registered as an insurance benefit in the national health insurance (NHI), it must go through five steps as a following figure, which takes about 1 year and 5 months in total.

**Figure 4 Procedure of NHI registration for health technologies.**



Source 4: 1. Ministry of Health and Welfare, Health Insurance Review and Assessment Services. (2019). Guidelines for evaluation on innovative medical technologies' eligibility for insurance benefits - AI-based medical technologies (radiology) & 3D printing technologies (혁신적 의료기술의 요양급여 여부 평가 가이드라인 - AI 기반 의료기술(영상의학분야) & 3D 프린팅 이용 의료기술) and

2. Ministry of Health and Welfare, Health Insurance Review and Assessment Services. (2020). Guidelines for evaluation on innovative medical technologies' eligibility for insurance benefits - AI-based medical technologies (pathology) (혁신적 의료기술의 요양급여 여부 평가 가이드라인 - AI 기반 병리학분야 의료기술).

Abbreviations: MFDS, Ministry of Food and Drug Safety. NECA, National Evidence-based healthcare Collaborating Agency. HIRA, Health Insurance Review and Assessment Services. MoHW, Ministry of Health and Welfare.



## **Step 1**

Firstly, MFDS examines a technology's safety and effectiveness and authorizes the product.

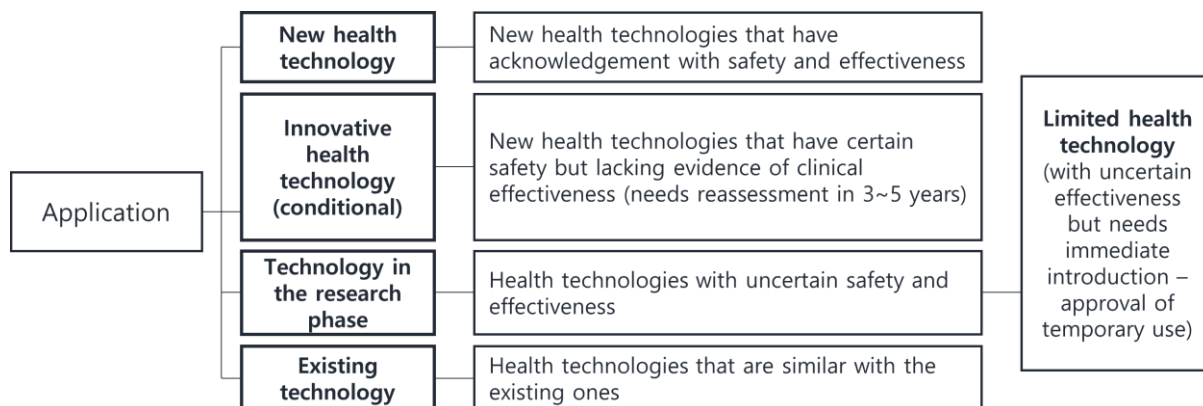
### **1) Step 2**

If a technology is approved by MFDS, then HIRA confirms if a recent technology is eligible for the new health technology assessment by NECA to reduce unnecessary assessment procedures and to make sure necessary technologies are included in the insurance system as soon as possible. A professional evaluation committee in HIRA compares its purpose and methods with existing technologies and notifies the result to the applicant and the New Medical Technology Evaluation Committee of NECA.

### **2) Step 3**

If the technology is identified as a new medical technology, then the New Medical Technology Evaluation Committee of NECA appraises its safety and effectiveness. There are four possible assessment results: 1) new health technology, which has acknowledgement with safety and effectiveness, 2) innovative health technology (conditional), which is a new health technology that has certain safety but lacks evidence of clinical effectiveness and needs reassessment in 3~5 years, 3) technology in the research phase, which has uncertain safety and effectiveness, and 4) existing technology, which is similar with the existing ones. Among the technologies in the research phase, limited health technologies that have uncertain effectiveness but need an immediate introduction to the clinical field can be allowed to be used temporarily on the condition of evidence data collection.

**Figure 5 Possible results of NECA's assessment.**



Source 5: 1. Ministry of Health and Welfare, Health Insurance Review and Assessment Services. (2019). Guidelines for evaluation on innovative medical technologies' eligibility for insurance benefits - AI-based medical technologies (radiology) & 3D print and 2. Ministry of Health and Welfare, Health Insurance Review and Assessment Services. (2020). Guidelines for evaluation on innovative medical technologies' eligibility for insurance benefits - AI-based medical technologies (pathology) (혁신적 의료기술의 요양급여 여부 평가 가이드라인 - AI 기반 병리학분야 의료기술).

\*Technologies that can be applied to the clinical field: new health technology, innovative health technology, limited health technology, existing technology

\*Technologies that cannot be applied to the clinical field: technology in the research phase (without Limited health technology)

#### 4) Step 4

Professional assessment committees of HIRA appraise the relative value and whether a new technology should be registered for the national health insurance benefits considering its medical validity, importance, treatment and cost-effectiveness, patients' financial burden, and social benefit. Currently, HIRA provides a guideline for the insurance benefit assessment on medical technologies based on Artificial Intelligence and 3D printing which has a high demand for health insurance applications.

### 4.2 Guideline for the assessment of national health insurance (NHI) coverage – AI medical imaging (radiology and pathology)

According to the guideline, AI medical imaging technology in radiology is a single software as a medical device (SaMD) based on artificial intelligence (AI) which is utilized as a part of medical

practice like image reading and clinical decision. And AI medical imaging technology in pathology is a technology to diagnose and interpret utilizing medical devices or software that analyzes pathological information of clinical specimens converted to digital data. MFDS's definition of medical devices with big data and AI applied are as follows.

**Table 7 MFDS' definition of medical devices with big data and AI applied.**

	<b>Definition</b>
<b>Medical software that is a medical device</b>	A software that diagnoses predicts, and monitors patients' disease state using clinical information (e.g., the size and location of a tumour) obtained by analyzing medical big data
	Software that provides clinical information needed to diagnose and treat patients by analyzing patterns and signals from the medical image, diagnostic devices based on medical big data
<b>Medical software that is not a medical device</b>	A software that assists the administrative work of the medical institute
	Software for daily healthcare like sports and leisure
	Software for education and research
	Software for the management of medical record
	Software that provides medical personnel with tools to organize and track patients' health information or medical information, or helps them to easily access medical information

Appropriate evidence that can show the characteristics and performance of a technology must be submitted to judge the similarity with the existing ones. If a new technology's performance is identified to be similar to human's/pathologist's analysis and its accuracy is approved through submitted evidence, then the technology is acknowledged as an existing reimbursement.

**Table 8 Level of evidence by the research methodology**

<b>Class</b>	<b>Research Methodology</b>
<b>Level 'Ga' (가)</b>	Expert opinion, case series, simple cohort study
<b>Level 'Na' (나)</b>	Retrospective comparison study

<b>Level 'Da' (다)</b>	Prospective comparison study Meta-analysis of retrospective comparison studies
<b>Level 'Ra' (라)</b>	Meta-analysis of prospective comparison studies Randomized prospective comparison clinical trials Cost-effectiveness research
<b>Common precondition</b>	<ul style="list-style-type: none"> <li>① The procedure of data acquirement for machine learning must be ethical.</li> <li>② Target patient group, methods to obtain a specimen, and the result of sensitivity and specificity verification must be specific.</li> </ul>

If the following are confirmed through the submitted evidence, then the technology becomes eligible for the new health technology assessment.

- When it provides new diagnostic information that existing technologies cannot provide (Category D)
- When it substitutes expensive existing health technologies (Category E)

**Table 9 Criteria for the judgement on qualification for the assessment**

<b>Class</b>	<b>Explanation</b>	<b>Result</b>
<b>Category A</b>	Assists in decipher <ul style="list-style-type: none"> <li>- improving doctors' work process</li> <li>- providing medical knowledge</li> <li>- Decrease in workload and the time required</li> </ul>	Existing reimbursement
<b>Category B</b>	Provides supplementary diagnosis information within the scope of the general examination's role	Existing reimbursement
<b>Category C</b>	Provides major diagnosis information within the scope of the general examination's role	Existing reimbursement

<b>Category D</b>	Provides latest information about the scope of the general examination's role	Eligible for the new health technology assessment
<b>Category E</b>	Substitutes existing expensive medical practice	Eligible for the new health technology assessment

### 4.3 Guideline for the assessment of national health insurance (NHI) coverage – 3D printing

3D printing health technology is a technology using medical devices produced by 3D printing. As this technology is used in surgeries, it is presented mainly in the field of surgery in the guideline.

**Table 10 Classification of 3D printing health technology**

<b>Classification</b>	<b>Definition</b>
<b>Surgery simulation</b>	To produce a customized model using 3D printing and to utilize them as a guide for the decision of diagnosis or treatment method
<b>Surgery guide</b>	To accurately resect or measure the length and angle of the part of the body
<b>Prosthesis</b>	To reconstruct or supplement the body's defect
<b>Orthosis</b>	To pressure and fix parts of the body

Like AI medical imaging, appropriate evidence that can show the characteristics and performance of a technology must be submitted to judge the similarity with the existing ones.

If the subject, purpose, and method of technology are similar to those of existing technology and only the production method is simply changed or there is little difference in innovativeness compared to the existing ones, technology is classified as 'Category A', which means it is not different with the existing insurance benefit. But even if a subject, purpose, and method of technology are similar to those of existing technology, if there is a significant change of value

like improvement of treatment effect and cost-effectiveness, then the technology is classified as 'Category B', which means it is possible to reclassify a technology within the range of existing insurance benefits.

On the other hand, if a subject, purpose, and method of technology are not like those of existing technology and there is a possibility of changes in safety and effectiveness, then the technology is classified as 'Category C,' which means it is eligible for a new health technology assessment.

**Table 11 Criteria for the judgement of qualification for the assessment**

<b>Class</b>	<b>Characteristics</b>	<b>Judgement</b>
Category A	<ul style="list-style-type: none"> <li>• A simple change in the production method</li> <li>• Minor difference in innovativeness compared to existing technologies</li> </ul>	Existing reimbursement
Category B	<ul style="list-style-type: none"> <li>• A noticeable value change in treatment results and cost-effectiveness</li> </ul>	Existing reimbursement (Consideration of reclassification)
Category C	<ul style="list-style-type: none"> <li>• The difference in subject, purpose, and method</li> <li>• A possibility of change in safety and effectiveness because of differences in subject, purpose, and method compared to existing technologies</li> </ul>	Eligible for the new health technology assessment

## 5. MAPPING RELEVANT STAKEHOLDERS

## **5.1 Digital health and healthcare system (14)**

As mentioned above, the importance and scale of digital health are growing fast in Korea, but there are still several problems to solve before absorbing it into Korea's healthcare system. In addition, as diverse stakeholders are included in the development and management of digital health, each field has a different point of view. Therefore, several studies have been done to make a consensus on establishing an appropriate direction and structure that can be agreed upon by as many stakeholders as possible.

Through an expert discussion on the digital health and healthcare system conducted by the Economic Information and Education Centre of KDI in May 2021, diverse and profound suggestions were drawn out. Regarding the current status of the healthcare system, there were concerns about the depletion of health insurance finances because of unnecessary consumption of medical resources. Also, there was an opinion suggesting that innovation of the healthcare system should be done considering a change of demographic structure to an inverted pyramid shape. And they emphasized that the role of digital health would be to solve these current problems of the healthcare system by saving costs and improving convenience, which would lead to a more equal and healthy society.

An expert from the industry said that to make this innovation a reality, companies need to try to accept positive regulations, and unnecessary ones should be improved. Also, the expert suggested that the government needs to contemplate how to make and manage a reward system that can encourage medical staff to produce medical data while examining and treating patients. Another expert from the industry suggested that the government should make institutional strategies to encourage small and medium-sized companies by giving them incentives or evaluating publicity.

## **5.2 Application of NHI on digital therapeutics**

To draw a consensus on the application of NHI to digital therapeutics, an interview with people from academia, industry, consumers, etc. was conducted as part of private research on digital therapeutics. Regarding the concept and the range of digital therapeutics, there was an

agreement that the NHI's coverage area should be limited to those that need a 'physician's prescription'. And there was a common opinion that digital therapeutics with sufficient treatment effectiveness need to be covered by NHI. However, there were various positions on whether selective coverage and how much of this coverage should be applied to them. Also, there was a difference of opinion on the criteria for the decision of coverage like non-inferiority compared to standard treatment, but it was difficult to get a clear view of specific indicators to evaluate the benefit of digital therapeutics. When it comes to the reward system, a method to apply some discounting rates considering the decrease in workforce was suggested, but they disagree with the possibility of pricing based on prime costs because of several reasons and difficulties in deciding detailed criteria to estimate prime costs. Also, some people argued that additional medical charges for procedures are needed to encourage treatment using digital therapeutics, but others considered it as a part of a fundamental medical fee.

## 6. EXAMPLES OF DIGITAL HEALTH TECHNOLOGY REIMBURSED BY THE NHI

Recently some digital therapeutics have been in the middle of clinical trials for the final approval of MFDS. Still, there is no digital health technology that is already registered for national health insurance benefits in Korea yet. Instead, a few examples related to digital health technologies have been registered for health insurance benefits.

**Table 12 Approval status of digital therapeutics' clinical trial plan<sup>1</sup>**

No.	Type	Description	Approval date
1	Cognitive treatment software	Improvement of visual field impairment in patients with brain	2019. 6. 13.

<sup>1</sup> Ministry of Food and Drug Safety promotes rapid commercialization with regulatory coordination in digital health field. (2022, April 15). Ministry of Food and Drug Safety.

[https://www.mfds.go.kr/brd/m\\_99/view.do?seq=46309&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=1](https://www.mfds.go.kr/brd/m_99/view.do?seq=46309&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1)



		injury	
2	Visual training software	Suppression of myopia progression in pediatric myopia patients	2021. 1. 21.
3	Respiratory rehabilitation software	Respiratory rehabilitation treatment for chronic obstructive pulmonary disease, asthma, and lung cancer patients	2021. 9. 3.
4	Cognitive treatment software	Insomnia treatment	2021. 9. 10.
5	Cognitive treatment software	Insomnia treatment	2021. 9. 27.
6	Rehabilitative treatment software	Upper extremity rehabilitation treatment for chronic stroke patients	2021. 10. 6.
7	Cognitive treatment software	Improvement of addiction disorder in alcoholic patients	2021. 11. 22.
8	Cognitive treatment software	Improvement of addiction disorder in nicotine addiction patients	2021. 11. 22.
9	Emotional disorder treatment software	Depression treatment for patients with depressive disorder	2021. 12. 23.
10	Emotional disorder treatment software	Treatment of anxiety disorders in patients with generalized anxiety disorder	2021. 12. 30.

### **Abbott – Freestyle Libre (15)**

Abbott's Freestyle Libre is a non-invasive continuous glucose monitoring (CGM) system that can measure and check the blood glucose level for fourteen consecutive days for a maximum.

Patients attach a coin-like pad sensor to the rear side of an upper arm, then a filament of the sensor is inserted right under the skin, and it measures blood glucose level through interstitial fluid every minute. After patients install an application and scan the sensor on their arm using smartphones, then the glucose level data are automatically stored in a cloud information system 'Libre View'.

It was first launched in the Korean market in May 2020 and registered for health insurance benefits for Type 1 diabetes patients in December 2020. It has a significant difference from existing methods in that patients do not need to do a finger blood test every time. In addition, they can check and store their consecutive blood glucose level data through their smartphones, which means that this can also be considered an example of digital health technology that is reimbursed by the NHI.

**Insurance registration status of treatment materials using 3D printing.**

MOHW and HIRA's guidelines for evaluating innovative medical technologies' eligibility for insurance benefits introduced some therapeutic materials produced by 3D printing for insertion into the body that are reimbursed by NHI. Among the materials, customized products were not reimbursed and only the remaining types were covered by the NHI as the following table shows.

**Table 13 Insurance registration status of treatment materials using 3D printing.**

No.	Company	Item name	Reimbursement
1	Medyssey	skull molding material	X
2	Medyssey	Intervertebral body fusion prosthesis	O
3	Medyssey	Intervertebral body fusion prosthesis	O
4	Medyssey	Artificial cheekbones	X
5	Medyssey	Artificial eye socket	X

6	T&R BIOFAB	Special material skull molding material	O
7	T&R BIOFAB	Special material skull molding material	O/X
8	SpinoTech	Intervertebral body fusion prosthesis	O
9	Medyssey	Intervertebral body fusion prosthesis	O
10	Medyssey	Orthopaedic products	X
11	T&R BIOFAB	Special material skull molding material	X
12	T&R BIOFAB	Absorbable periodontal tissue regeneration inducer	O
13	PIMS	Intervertebral body fusion prosthesis	O
14	Healthcare Solutions	Special material skull molding material	O
15	Cusmedi	skull molding material	X
16	Cusmedi	Artificial eye socket	X
17	Cusmedi	Artificial cheekbones	X
18	PIMS	Intervertebral body fusion prosthesis	O

## 7. CHALLENGES AND OPPORTUNITIES IN KOREA

In summary, Korea is facing some challenges to overcome, but at the same time, it has some strengths and opportunities that can activate and foster digital health.

### **Challenges:**

- Convenient access to medical facilities leads to less need for telemedicine
- Several regulations hinder the invigoration of digital health (e.g., regulations on big medical data, telemedicine, and direct-to-consumer DNA tests)
- Diagnosis/treatment-oriented system rather than preventive-focused system
- Unclear consensus on the payment and reward system for digital health or therapeutics
- No specific standard method to evaluate the clinical effectiveness of digital health technologies
- The relative digital divide in information-vulnerable groups

### **Opportunities:**

- Superb medical human resources and infrastructure can be a foundation for the development of digital health
- Advanced ICT technologies and ubiquitous mobile Internet environment
- Revision of enforcement rules and enactment of guidelines
- The governmental movement to foster digital health (e.g., Korean New Deal 2.0, Health Plan 2030, etc.)

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## Abbreviations

AI	Artificial Intelligence
EMR	Electronic medical record
HIRA	Health Insurance Review and Assessment
KDI	Korea Development Institute
K-eHEALS	The Korean eHealth Literacy Scale
KHIDI	Korean Health Industry Development Institute
KIET	Korea Institute for Industrial Economics & Trade
KISTEP	Korea Institute of S&T Evaluation and Planning
MFDS	Ministry of Food and Drug Safety
MOHW	Ministry of Health and Welfare
NECA	National Evidence-based healthcare Collaborating Agency
NHIS	National Health Insurance System
NIA	National Information Society Agency
SaMD	Software as a medical device

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