APACMed
The voice of MedTech

IN PARTNERSHIP WITH

KMDIA 사단법인 한국의료기기산업협회
Korea Medical Devices Industry Association

Skill up with APACMed: How to get digital health reimbursed in Korea?

THE WEBINAR WILL BE IN KOREAN

Friday, 25 Mar 2022

2pm – 3pm (GMT+9)

About APACMed

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed 亚太 医疗技术协会) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific. APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory convergence. Learn more about the association at **www.apacmed.org**

230

Member companies

20 Of the top 30 MedTech Companies worldwide

130 Startup members

Korea Medical Devices Industry Association

About KMDIA

Established in 1999, Korea Medical Devices Industry Association(KMDIA) is a trade association that leads advocacy rights of the medical devices industry and contributes enhancing global competitiveness of member companies. We represent over 1,000 member companies including manufacturers, importers, suppliers and other stakeholders etc. and they account for more than 70% of Korean medical devices industry.

www.kmdia.or.kr

About the APACMed Digital Health Committee

250+ MEMBERS
from **75+ COMPANIES:**
MNCs, SMEs,
Start-ups

OUR MISSION
Support APACMed members across the entire digital health product journey, from regulatory approval to market access and use.

Roberta Sarno
Manager
APACMed Digital Health

Board Sponsor:
Elisabeth Staudinger
CEO Siemens Healthineers APAC

OUR VALUE
Share the voice of the industry with the public and private digital health deciders and provide a neutral platform for public-private collaborations on regulatory, cybersecurity, reimbursement, health data, interoperability.

4

APACMed's work in digital health reimbursement

Between 2020 and 2021, the APACMed digital health committee published 2 papers and 2 reports on digital health reimbursement:

1. **Harnessing the potential of digital health technologies – policy pathways for value assessment and reimbursement** (link)
   - A position paper with recommendations to policymakers on the implementation of fit-for-purpose value assessment, funding and reimbursement framework for clinical-grade digital health technologies.
2. **Advancing remote healthcare during and post COVID-19** (link),
   - A paper summarizing learnings from dialogues between APACMed and private and public sector on remote care management programs in Asia.
3. **A new framework for digital health reimbursement** (link to full report and white paper)
   - A collection of use cases with the strategies that MedTech companies adopt to reimburse or monetize their digital health solutions in Asia.
4. **Overview of country Health Technology Assessment (HTA) guidelines for digital health technologies** (link)
   - A report which analyses digital health-specific HTA guidelines existing in Korea, France, Belgium and the U.K.

APACMed's work in digital health reimbursement

With these documents, **we review the status of digital health reimbursement and monetization approaches** in Asia and beyond, highlight best practices and gaps, and i**nvite policymakers and payors to implement fit-for-purpose value assessment, funding, and reimbursement frameworks for digital health** to improve access to patients and economic sustainability.

Today's agenda and speakers

Korea Time	Session	Speaker
2:05 am 15 Min	Value assessment and reimbursement of digital health technologies in Asia: best practices, gaps and use cases	Jaehyun Suh, KRPIA
2.20 pm 10 Min	Evaluating digital health in Korea	Prof. Jeonghoon Ahn, Ewha Womans University
2.30 pm 15 Min	Measuring the value of digital health – The HCP perspective and next steps for the government	Prof. Jae-Yong Shin, Yonsei University
2.45 pm 10Min	Industry position	Jae-Eun Myung, Medtronic, KMDIA, APACMed
2:50 pm 5 Min	Closing remarks and next steps for APACMed	Sang-Soo Lee, Medtronic, KMDIA, APACMed

Jaehyun Suh
Healthcare Policy Manager @KRPIA

Value assessment and reimbursement of digital health technologies in Asia: Best practices, gaps and use cases

Value assessment of digital health

APACMed conducted a comparative analysis of HTA framework specific to digital health in Asia and Europe.

Value assessment of digital health

France

Guide to the specific features of clinical evaluation of a connected medical device (CMD) in view of its application for reimbursement via LPPR[1]

Condsiderations

Are considered connected medical devices (CMDs):

- Devices intended for use for medical purposes (CE-mark)
- Devices for individual use (implanted or used by patient)
- Devices requesting reimbursement by the National Health Insurance

Reimbursements

Assessment criteria for Reimbursement

Evidence standards evaluated by the CNEDiMTS[2] have to demonstrate:

- Individual benefits: morbidity-mortality, patient or carer's benefits, or any related and validated measurement tool supporting the product's claim
- Other benefits, related to the stakeholders' contributions (accessibility, care practice and organisation, quality of care, safety)
- Lack of harmful effect on the individual

Reimbursement (LPPR)

The reimbursement decision would be based on the actual clinical benefits (ACB) and the added clinical value (ACV), if sufficient ACB. The ACV will be a key contributing factor to price negotiations with CEPS[3], to be listed in the LPPR.

Authors: CNEDiMTS (Medical device and Health technology Evaluation Committee) of HAS (Haute Autorité de santé)

Published in January 2019.

Value assessment of digital health

Germany

The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V

Considerations

DiGA (Digitale Gesundheits-anwendungen) is a medical device of the risk class I or IIa (MDR/MDD CE-marks). Its main function is based on digital technologies. The DiGA has to be used by the patient only or by the patient and the HCP.

To be listed in the directory, a DiGA must meet the following requirements:

- Product qualities – Safety and Suitability for use, functionality, quality, data protection, information security, interoperability, etc.
- Positive healthcare effect – Medical benefit and Patient-relevant improvement of structure and process

Reimbursements

If the DiGA already has a comparative study demonstrating a positive healthcare effect, it can apply for final listing for reimbursement. If not, it undergoes a preliminary testing period of 12 months, during which statutory health insurances will reimburse the costs provisionally.

Authors:

Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), Federal Ministry of Health (Bundesministerium für Gesundheit, BMG)

Published in April 2019

Value assessment of digital health

South Korea

Guideline for the national health insurance (NHI) coverage – eligibility for Innovative Health Technology Assessment Track

To date, South Korea is the only country in APAC that has developed a value assessment and reimbursement guidelines for DHTs.

Considerations

Scope: Innovative medical technologies

- Currently only artificial intelligence (AI) medical imaging, and 3D Printing
- To be updated for other innovative technologies including Digital Health Technologies (DHTs)

Reimbursements

Assessment criteria for Reimbursement

According to the level of improvement in clinical utility and cost effectiveness, DHTs are classified from Level 1 to 4.

Separate additional reimbursement price is granted to Level 3 and 4:

- Level 3 – Clinically significant improvement in treatment outcomes or diagnostic abilities / new diagnostic value and treatment effectiveness.
- Level 4 – Cost-effectiveness is clinically and significantly demonstrated in addition to Level 3.

Reimbursement of digital health has so far been difficult, for a number of factor including lack of reimbursement pathways and difficulties in demonstrating value

Because of the lack of clear reimbursement pathways and HTA guidelines, many DH technologies are paid by patients out-of-pocket or offered for free by manufacturers, **limiting innovation and adoption**

Developing structured access and reimbursement pathways for DH will have a number of **positive effects for the healthcare industry across multiple stakeholders types**

In APAC, specifically, reimbursement and HTA **guidelines for DH are limited**, and DH solutions are often **regulated as medical devices**

Our analysis shows that a regional strategy is lacking, even though COVID-19 has forged governments to switch to digital

Public frameworks existing in only 6 countries: Australia, China, Japan, South Korea, Taiwan and Thailand, covering a **variety of therapeutic areas** and based on **full payment, co-payment and per hour/visit charges**
Singapore, Vietnam and India have some policies to allow DH to get reimbursed by private health insurances.

CHINA
Reimbursement proves to be the Achilles heel in China's DH strategy.

KOREA
Korean policies regulate the reimbursement of a large variety of DH solutions.

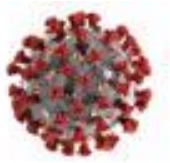
THAILAND
Despite an extensive telemedicine programs established by 2017, insufficient reimbursement schemes limit adoption.

SINGAPORE
Singapore lacks of proper reimbursement schemes.

JAPAN
COVID-19 spurs much needed changes in Japan's digital health reimbursement schemes.

TAIWAN
Taiwan banks heavily on digital health to fight COVID-19.

AUSTRALIA
The most mature digital health market in APAC leads the way for Digital Health Reimbursement.



COVID-19 has forced governments to switch to digital health to prevent nosocomial infection

Impact of COVID-19 on government initiatives

Australia
- Australia included almost all therapeutic areas to the Medicare reimbursement scheme till October 2020, which provides up to 85% reimbursement for telehealth.

China
- China's health ministry released a directive which allows "full pay" for all telemedicine consultations.

Korea
- South Korea which had previously banned telemedicine, legalized telemedicine temporarily.

Japan
- Doctors can be consulted online for a first/not regular examination, even if the medical need doesn't meet conventional conditions.

Reimbursement policies currently cover Telemedicine, Remote monitoring, AI, 3D printing, SaMD and Robotic surgery

TELEMEDICINE

REMOTE MONITORING

SaMD

AI

ROBOTIC SURGERY

3D PRINTING

- Reimbursement policies currently cover Telemedicine, Remote monitoring, AI, 3D printing, SaMD and Robotic surgery
- **Telemedicine** is the most often reimbursed technology, being covered by national health insurers in Australia, China, Japan, Korea, Taiwan and by private in Singapore and Vietnam
- **Remote monitoring** is the second most reimbursed technology, with dedicated frameworks in Australia, Korea and Japan.
- **Smart infusion pumps** - which are used for a variety of purposes from diabetes to cancer – are reimbursed in Korea, China and Thailand
- **Robotic surgery and teleradiology** are reimbursed in Korea

We prioritised 15 use cases and profiled them to identify tactics to favour the reimbursement and monetization DH

Product	Manufacturer	Use case	Digital health component	Customer / Payer type	Geographical origin	Commercial availability in APAC[1]	APAC countries reimbursed
HeartFlow Analysis	**HeartFlow**	AI imaging – cardiology	Software	Hospitals / Public payer	US	JP	JP
da Vinci Robotic	**Intuitive Surgical**	Robotic surgery	Coupled with medical device		US	Across APAC	JP, KR
FreeStyle Libre	**Abbott**	Glucose monitoring system		Patients / Public payer	US	Across APAC	JP, KR, AU[4]
Space Pump	**B Braun**	Smart treatment		Hospitals / Public payer	DE	Across APAC	KR, TH, CN (specific provinces)
Merlin@Home transmitter	**Abbott**	Remote home monitoring		Patients / Public payer / Private insurers	US	Across APAC	AU[4]
VNS Therapy System	**Liva Nova**	Treatment - Neuromodulation			UK	Across APAC	JP, AU, TW, KR
Propeller sensor	**Propeller Health**	Smart treatment			US	Across APAC[2]	Not publicly reimbursed[5]
Welwalk Robotic System	**Toyota and Fujita Health Uni. Hospital**	Robotic system		Hospital service providers	JP	JP	
Selena+	**EyRIS**	AI imaging – ophthalmology	Software		SG	SG, MY	
iBreastExam	**UE Lifesciences**	Breast cancer diagnostics	Coupled with medical device		US	Across APAC	
Ultrasound iQ	**Butterfly Network**	Smart imaging			US	ANZ	
InferRead solutions	**Infervision**	AI imaging – multiple diseases	Software		CN	CN	
Avellan OPM Technology	**Avellan**	BP and heart rate monitoring	Coupled with medical device	Hospitals / Patients / Private insurers	UK	Across APAC[3]	
Neurotrack cognitive assessment	**Neurotrack**	Digital therapeutics	Software	Patients / Private insurers	US	JP	
Kardia Mobile	**Kardia**	ECG Monitoring	Coupled with medical device	Patients	US	Across APAC	

Note: 1) Based on publicly available information and interviews with company representatives for selected companies, products commercialized across APAC are likely to be found in the key markets like CN, KR, JP, IN, TW, ANZ, and SEA; 2) Expected to be commercialized in APAC in 2020; 3) Avellan OPM technology is currently progressing FDA / CE registration; commercialization plans are still being developed; 4) Private reimbursement; 5) Not publicly reimbursed, and used for by other customer types such as hospitals, physicians, or patients;

Use case: Abbott *FreeStyle Libre*

Value Proposition

HCPs / Physicians: Facilitates better treatment decision through the data gathered
Patients: Convenience, Disease management
Public payer: Reduction in cost (e.g., reducing the likelihood of debilitating comorbidities

Japan: Reimbursed in Aug 2017
Real world use data demonstrated that people using FreeStyle Libre spend less time in hypoglycemia or hyperglycemia

US: Reimbursed in Jan 2018
patient co pay 20%

Canada: Reimbursed in Sep 2019
First sensor-based glucose monitoring system to be listed by any provincial health plan in Canada

Reimbursement progress

UK: Reimbursed in Nov 2017

Korea: Reimbursed in Jan 2019
CGM are reimbursed 70% for people with type 1 diabetes in Korea, while the remaining 30% is paid by patients

Australia: Reimbursed in Mar 2020
Listed on the National Diabetes Services Scheme - fully subsidized for eligible citizens living with Type 1 diabetes

Use case: Abbott *FreeStyle Libre*

Reimbursement: Key findings

Gained strong advocacy by clinical societies and patient groups

In Australia,
- The expanded reimbursement coverage decision for CGM devices has been driven by efforts of patient and professional advocacy organizations

In Korea
- Patient advocacy, supported by organizations like Korean Diabetes Association, Korean Pediatric Diabetes Association led to changes in nation wide policies related to reimbursement of medical devices (including CGM)

Demonstrated strong clinical evidence with positive outcome

In Japan and the UK
- Real world use data was presented, demonstrating that people using FreeStyle Libre were able to scan their glucose levels more frequently and spend less time in hypoglycemia or hyperglycemia, hence able to achieve improved glucose control overall

Collaborated with private insurers

- Prior to reimbursement by Medicare in the US, ~98% of commercial insurers already recognized the value of FreeStyle Libre and provided coverage for policyholders

Based on the use cases analysis, we developed a Best Practices Framework, which can used by companies for their DH solutions

	Best practices	*Type*
D	Develop understanding of local reimbursement requirements, including 'unofficial' practical considerations	Similar to medical devices
I	Invest in initiating HTA and cost-effectiveness studies for key markets early to justify product pricing	
G	Generate superior clinical evidence against the existing standard of care	
I	Invest in market creation and market acceptance of digital health products	Tailored to DH
T	Target existing reimbursement codes first and concurrently assess feasibility of gaining new reimbursement codes	
A	Attain advocacy through known digital champions	
L	Land partnerships that offer access to valuable datasets	
L	Look for alternative funding sources for digital health products	
E	Embrace a monetization model that considers the unique nature of the digital health product	

Prof. Jeonghoon Ahn
Researcher Department
of Health Convergence
@EWHA

Measuring the value of digital health – The HCP perspective and next steps for the government

INNOVATION EWHA

Evaluating Digital Health in Korea

March 25, 2022

Jeonghoon Ahn

Department of Health Convergence

이화여자대학교
EWHA WOMANS UNIVERSITY

Korean Digital Health

National Agenda on Telehealth

- Korean governments have pursued digital health as a national policy agenda for the last decade
  - To provide an access to healthcare for those who do have a healthcare access issue (e.g. living in a remote island without a medical clinic) and who are not managed well (e.g. chronic disease patients does not come in to clinics)
  - To promote domestic industry in the field
  - To support Korean hospitals abroad

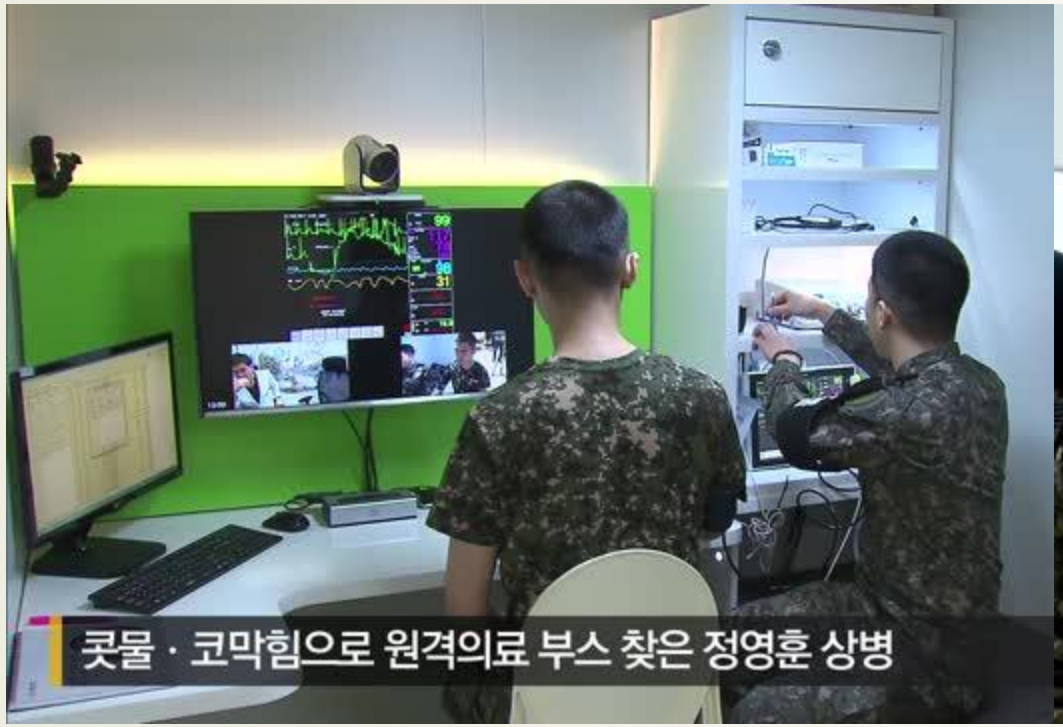
TELEHEALTH MODELS CONSIDERED

SPECIAL NEED BASED MODEL

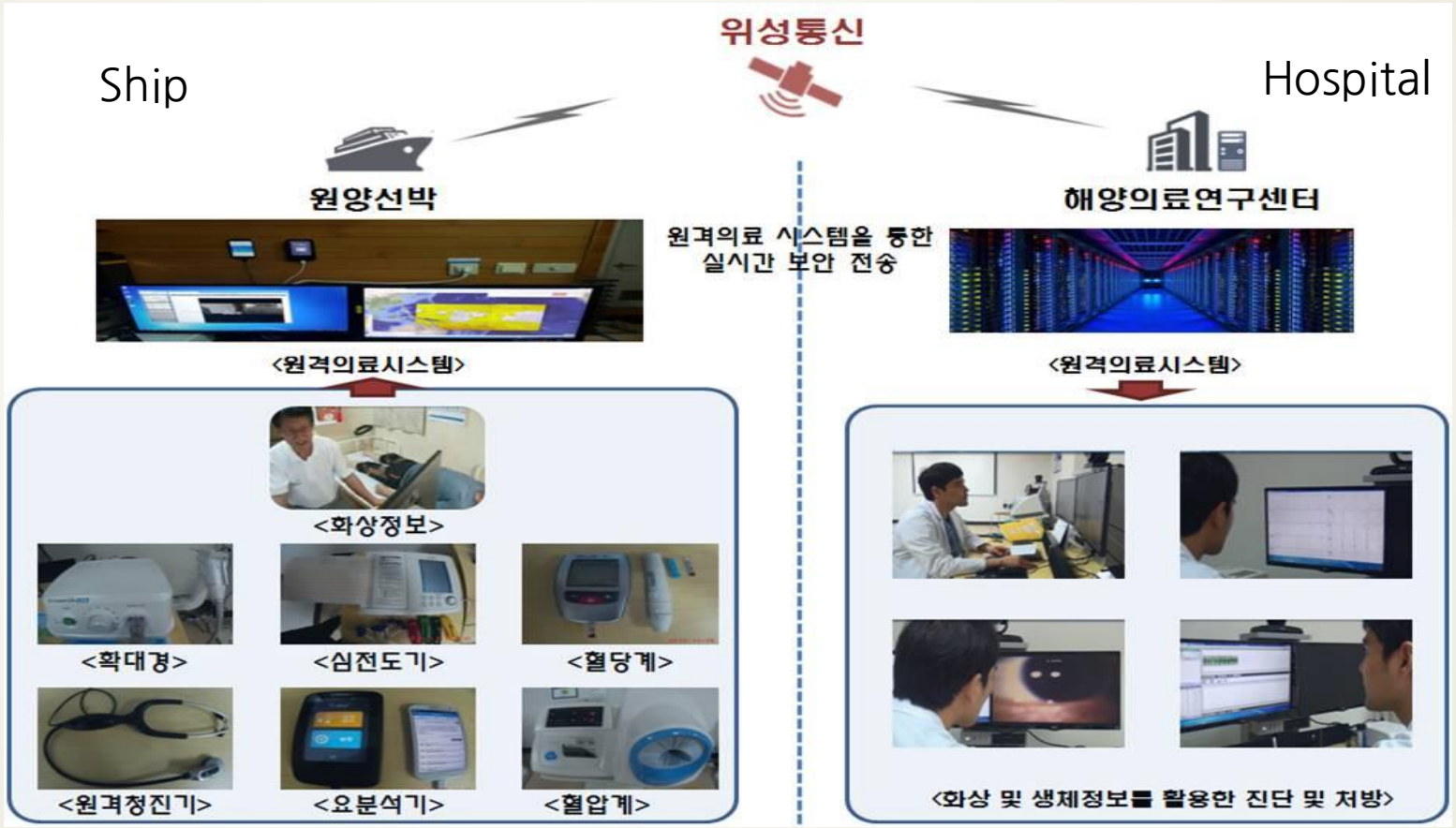
In the military service

For the merchant marines and seamen

Military GP



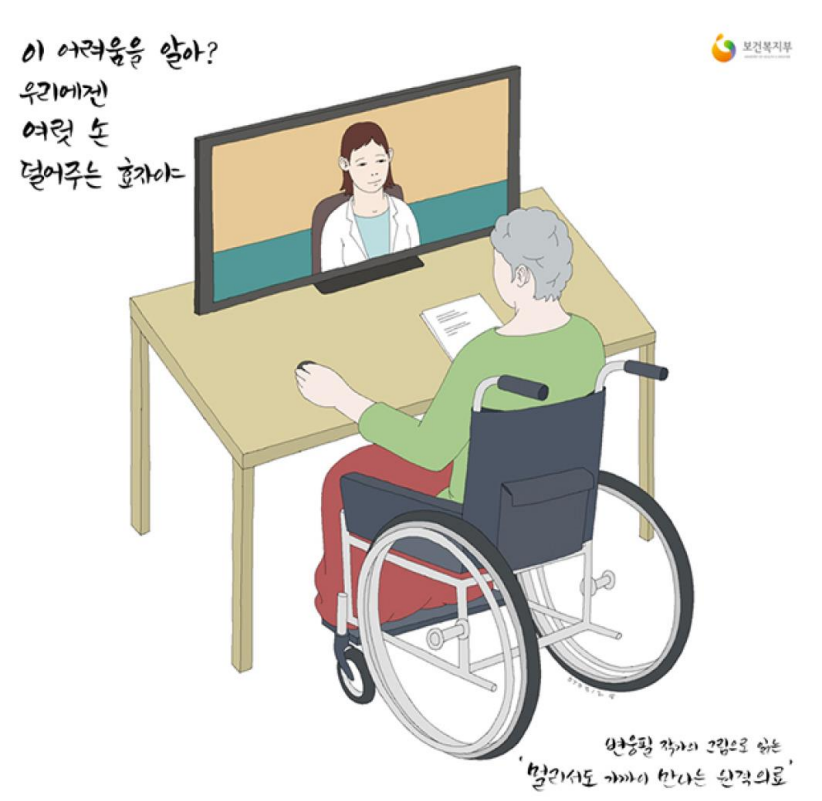
Marine Telehealth



TELEHEALTH MODELS CONSIDERED

SPECIAL NEED BASED MODEL

In the long-term care facility



In the remote village

Telehealth Booth

Telehealth Booth

국제 의료기기·병원설비 전시회(KIMES)가 5일 서울 삼성동 코엑스에서 열렸다. 비트컴퓨터 직원이 부스형 원격진료 시스템을 시연하고 있다. 비트컴퓨터 제공

Difficulties in Rural Area Health System

- As the population in the rural area decreases, hospitals suffer from financial problems
  - It is difficult to maintain emergency care units
- Medical professional school system and increase in female medical students accelerated the shortage of public doctors
- Young doctors do not want to work in the rural area

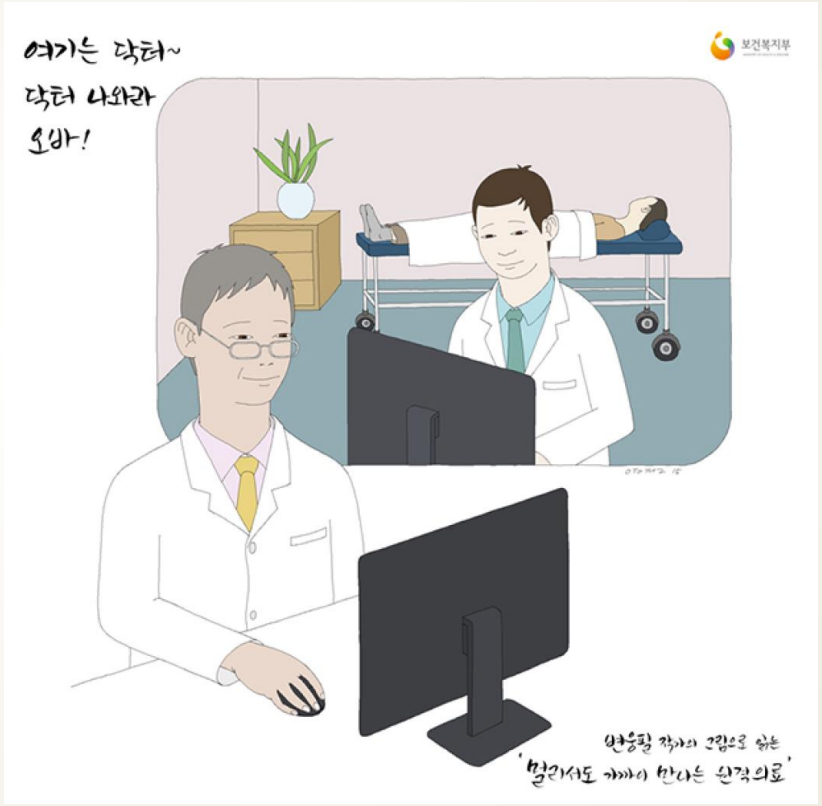
Solutions to the rural area health problems

- Remote consultations
  - Doctor to doctor setting
  - Rural doctor consult with an experienced doctors in other regions
- Doctor helicopter
  - Transport emergency patients quickly to the tertiary hospitals
- Telehealth

Doctor Helicopter

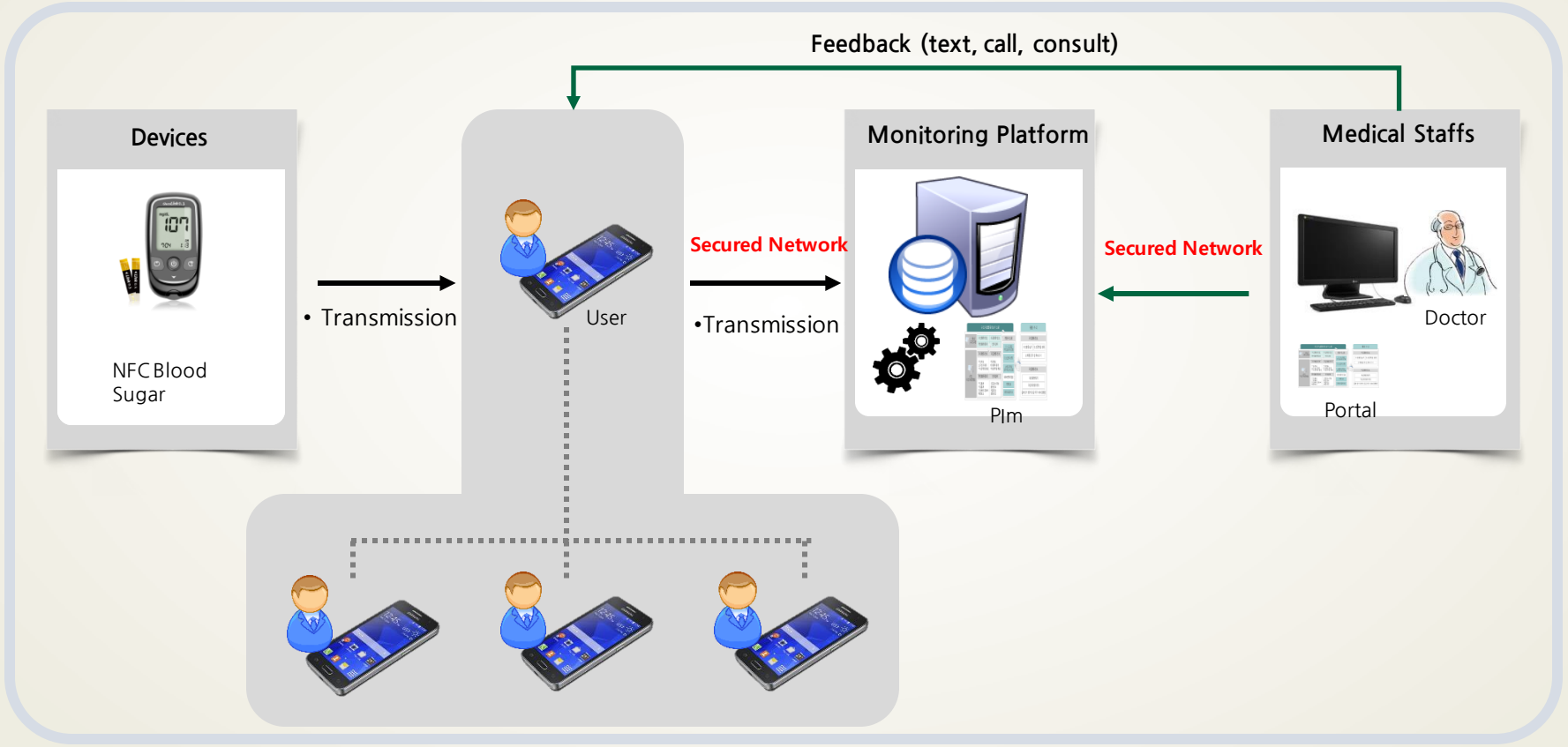
TELEHEALTH MODELS CONSIDERED

BETTER MANAGEMENT MODEL

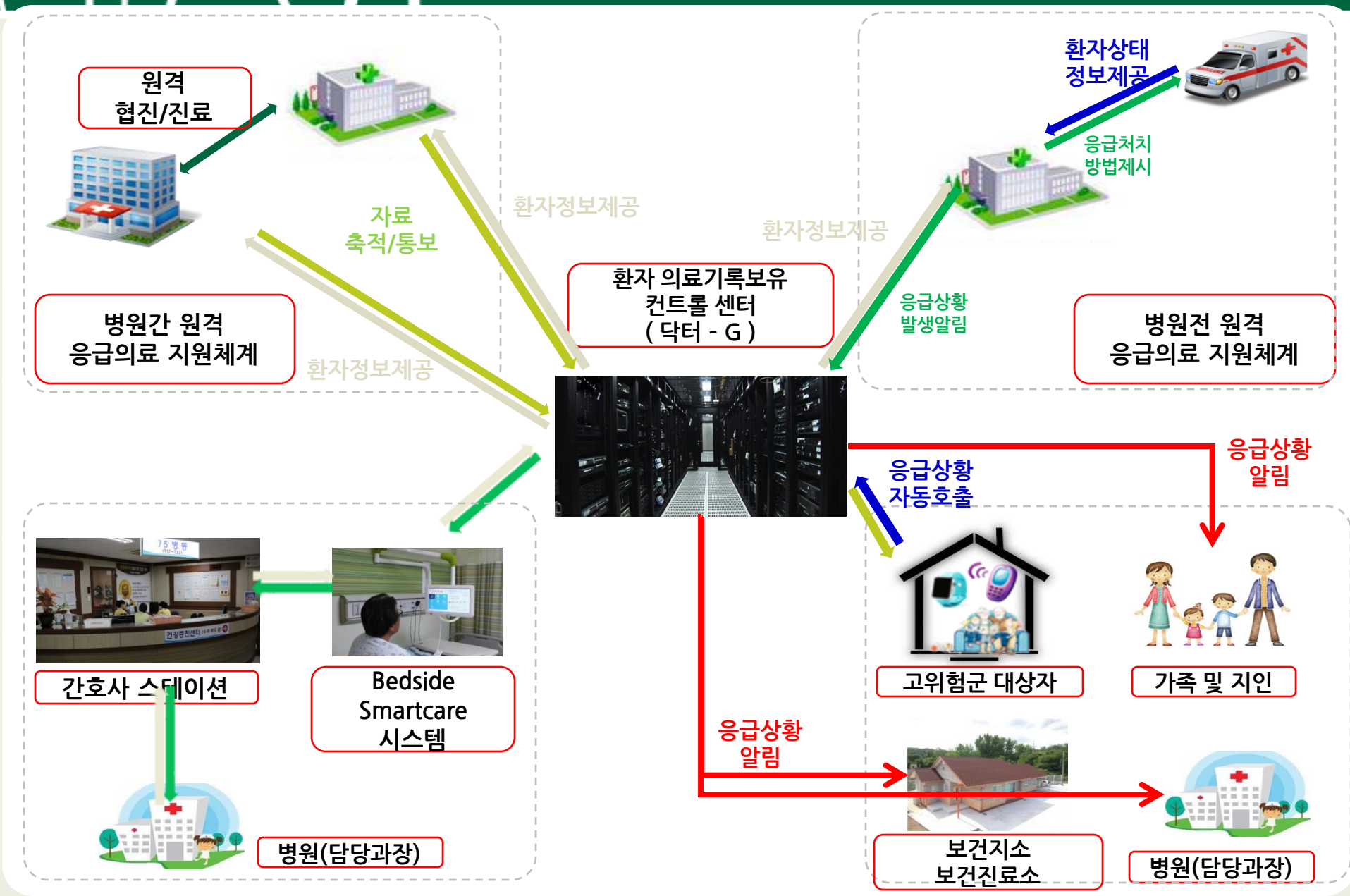


TELEHEALTH MODELS CONSIDERED

COMMUNITY BASED MODEL



Future System



RCT on Diabetes Managemen

COMMUNITY BASED MODEL

Setting		Intervention (N=145)	Control (N=94)	p-value
Baseline (A)	Mean±SD	7.98 (±0.78)	7.91 (±0.75)	0.4803
At 3 months (B)	Mean±SD	7.35 (±0.82)	7.63 (±0.95)	<0.05
Difference (B-A)	Changes	△0.63 (±0.81)	△0.27 (±0.71)	<0.05
	p-value	<0.05	<0.05	-

△: decrease

- Diabetes patients randomized and compared for m-health intervention vs routine care
- More significant decrease in HbA1C reported

Hypertension Management

COMMUNITY BASED MODEL

Setting			Baseline	At 3 months	BP change (p-value*)
Total (N=288)	SBP	Mean±SD	131.32±13.74	128.09±14.31	△3.24 (p < 0.05)
		Median [Q1,Q3]	130 [121, 140]	126 [119, 137]	△4
	DBP	Mean±SD	81.33±9.64	81.11±9.88	△0.22 (p = 0.74)
		Median [Q1,Q3]	80 [75, 88]	80 [75, 88]	0

BP: Blood Pressure, SBP: Systolic BP, DBP: Diastolic BP
△: decrease
* paired t-test

For hypertension patients in treatment managed by m-health showed statistically significant reductions in BP: SBP by 3.24 mmHg and DBP by 0.22 mmHg

- In subgroup of baseline 140 > SBP ≥ 130 mmHg (N=65), the decrease was 8.25 and 0.97 mmHg
- In subgroup of baseline SBP ≥ 140 mmHg (N=66), the decrease was 15.39 and 4.36 mmHg
- In subgroup of monitoring compliance > 75% (N=205), the decrease was 3.90 and 0.94 mmHg while less than 75% group (N=83), the decrease was 1.60 and -1.54 mmHg (not significant)

Patient Adherence on Pharmaceutical Therapies

- In management of chronic diseases, patient adherence on pharmaceutical therapies are key success factor
- M-health management of chronic patients seem to increase adherence on pharmaceutical therapies
- Many patients find in helpful to receive feedback on their BP or BG values (motivation)

Professional Society Opposition

- Strongly against telehealth and m-health
  - Especially the community based ones
  - M-health/telehealth cannot be cost effective
  - For those countries allowing m-health / telehealth has shortage in doctors but Korea does not have shortage
  - Safety concerns
  - Patients must see doctors!

Thank you !


Gracias
Danke
Tak
Gràcies
Obrigado
Terima kasih
धन्यवाद
Dankjewel
Grazas
谢谢
Kiitos
謝謝
Merci
Eskerrik asko
Dziękuję
Grazie
Takk
Go raibh maith agat
Ačiū
Dziękuję
Mauruuru koe
ありがとう
감사합니다
Tack
Спасибо

Prof. Jae-Yong Shin
Assistant Professor
@Yonsei University Digital Health

Measuring the value of digital health – The HCP perspective and next steps for the government

How to measure the value of digital health

The HCP perspective and next steps for the government

2022. 3.25.

Dept. of Preventive Medicine,
College of Medicine, Yonsei University, Seoul Korea

Jaeyong Shin, MD, MPH, PhD

연세대학교
YONSEI UNIVERSITY

목 차

디지털 치료란 무엇인가?

Introduction

The HCP perspective and next steps for the government

1 Background

2 Environmental change in Korea

3 Importance of Digital Adaptation

I. Background

Digital healthcare that adds value rather than comparison

I. Background: meaning for HCP

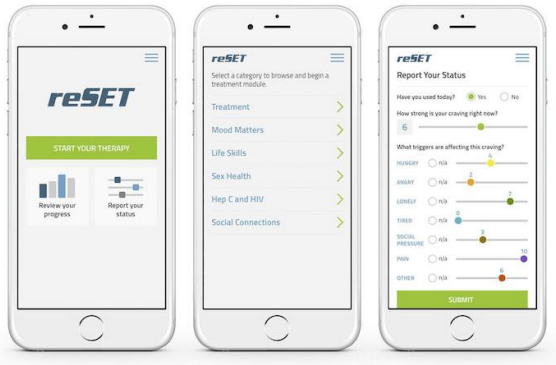
Building Better Practice

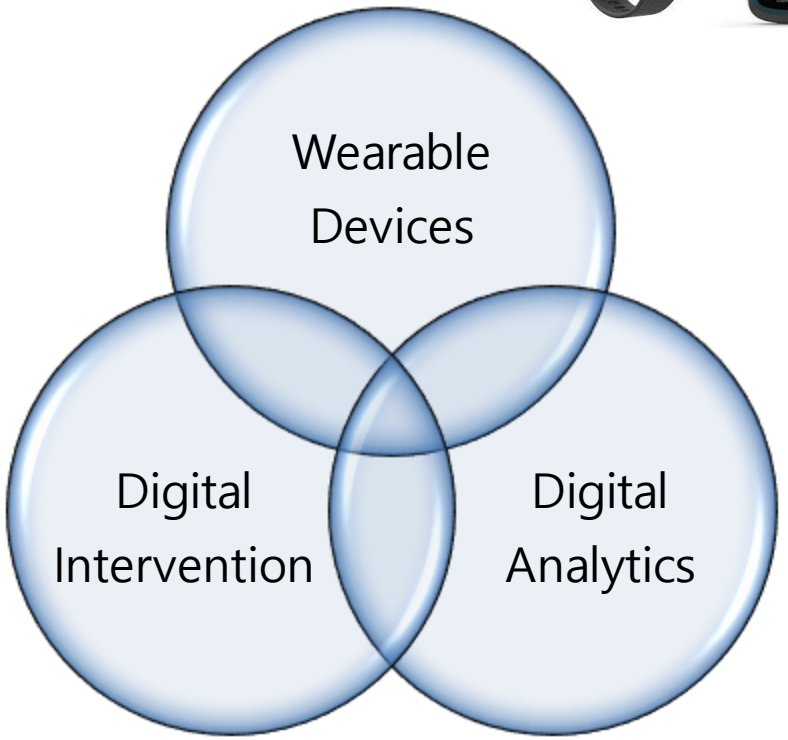
Digital health is

- the **convergence** **of digital technologies** with
- **Health, healthcare, living**, and **society**
- to enhance **the efficiency** **of healthcare delivery**
- and make '**medicine**' **more** **personalized and precise**

I. Background: what we can use

PEAR THERAPEUTICS





VUNO

Lunit

I. Background: what value we will transfer

What is your value?
Just clock? Or clock-based notifying schedule?

Introduction

The HCP perspective and next steps for the government

1 Background

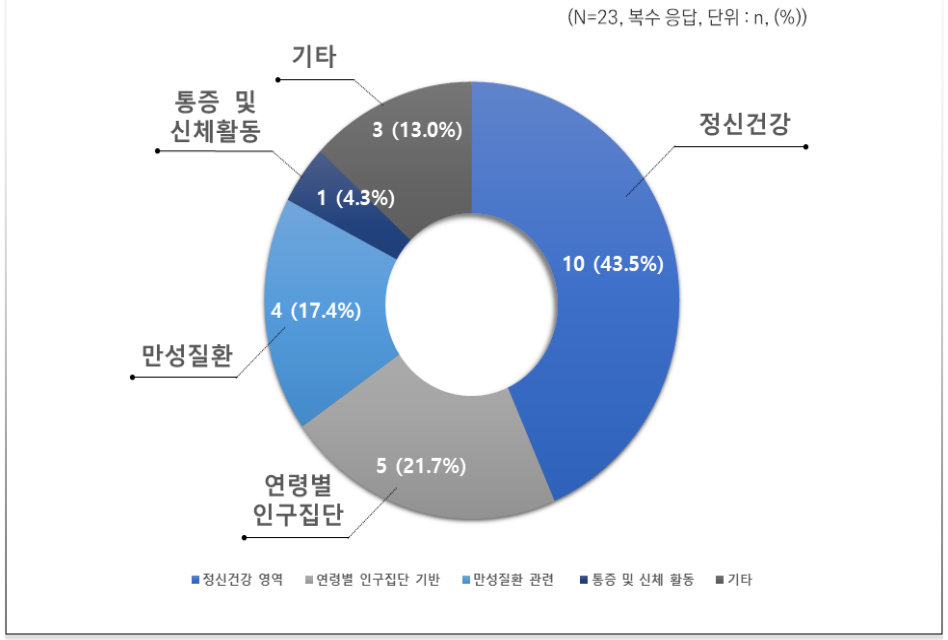
2 Environmental change in Korea

1.2. Environment change in Korea

With the domestic growth for Digital Therapeutics(DTx), it is necessary to develop national evaluation system

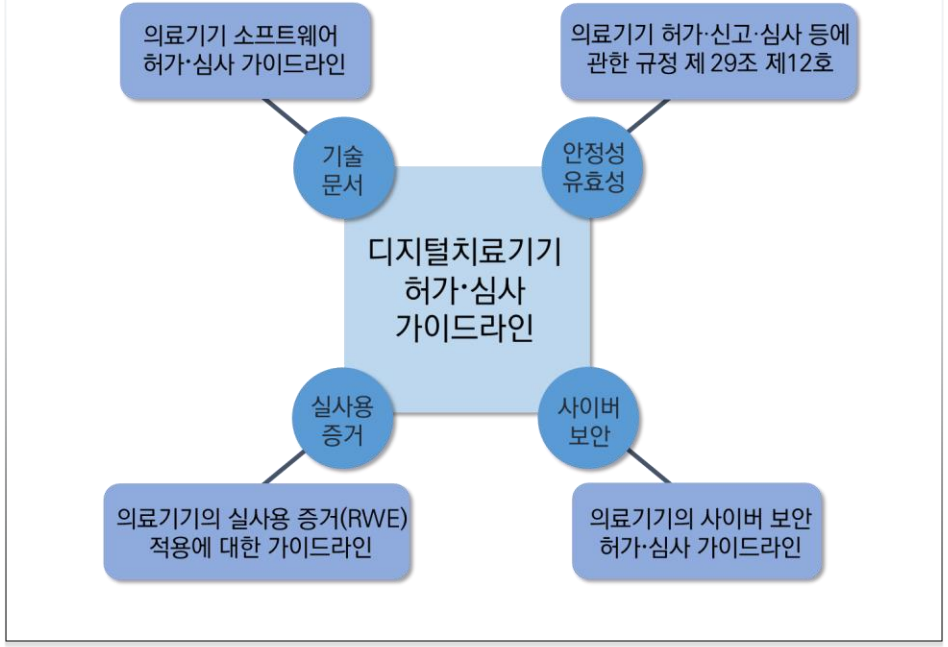
- (Economic) The domestic DTx market is expected to grow with annual rate of 20%, to reach 200 billion KRW in 2025
- (Policy) Requiring preemptive production of specific and systematic clinical trial protocols for approval and review
- (Technology) Reflecting the DTx specific characteristics to provide prompt support
- (Industry) Providing expert knowledge-based feedback to companies developing DTx

Increases in the number of DTx pipelinesP



출처: 내부 연구진-디지털헬스케어산업협회 공동 조사 자료, 2020.11. (대외비)

e-existing Digital Specific Regulations in Ko



출처: 디지털치료기기 허가심사가이드라인, 2020, 식품의약품안전처

1.2. Environment change in Korea: COVID-19 Pandemic

Uncomfortable, because of lock-down → However, *not so bad!*

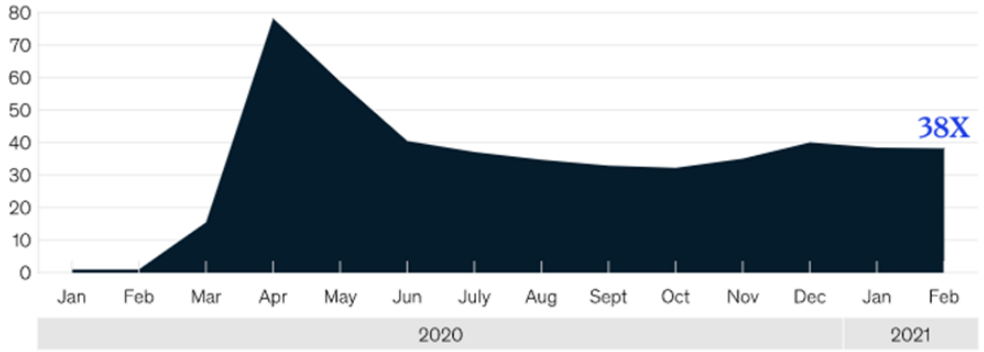
(A) Boeing

(B) Amazon

1.2. Environment change in Korea: COVID-19 Pandemic in the US

Uncomfortable because of limited accessibility →However, telehealth is fair enough

In the United States, the amount of telehealth rose up to 78 times and then stabilized at 38 times.



Source: Telehealth: A quarter-trillion-dollar post-COVID-19 reality?, McKinsey & Company, Jul, 2021.

Stock trends of Teladoc, the largest telehealth company in the US

1.2. Environment change in Korea: COVID-19 Pandemic in the US

Questions raised after Telehealth Services

Does Telehealth provide as much or better care than face-to-face care?

Does telemedicine ensure equal access improvements for all?

Wouldn't telemedicine actually lead to medical overuse?

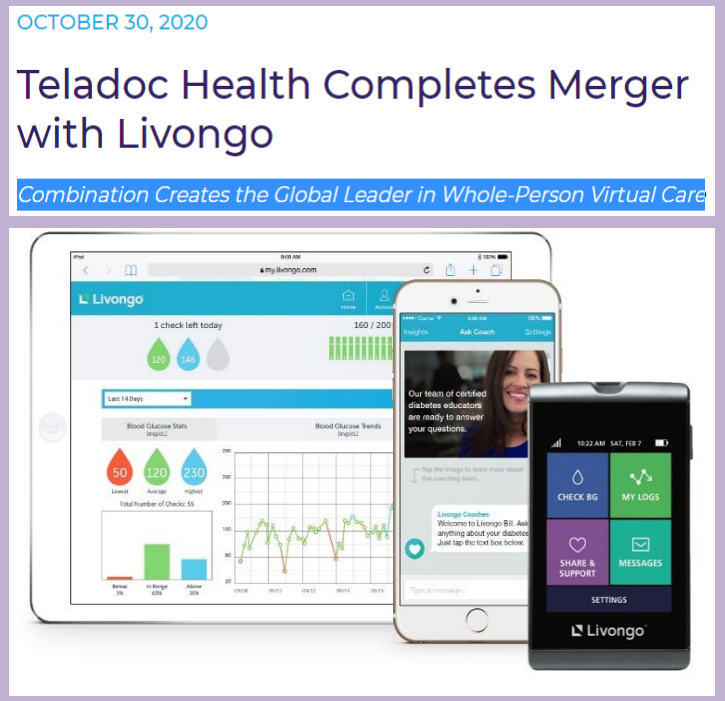
Wouldn't telemedicine become a vehicle for fraudulent claims or insurance fraud?

Source: Four Questions Telehealth Companies Must Answer To Ensure Long Term Growth, Joseph, Mar, 2021, Forbes.

1.2. Environment change in Korea: COVID-19 Pandemic in the US

Recognizing telehealth as a component of the care, rather than a simple static and ad hoc means

- **Non-face-to-face services must have more than basic elements to be included in health insurance**
- **Non-face-to-face service provides patient-centered health services with services such as prevention, management, rehabilitation, and follow-up in addition to treatment**

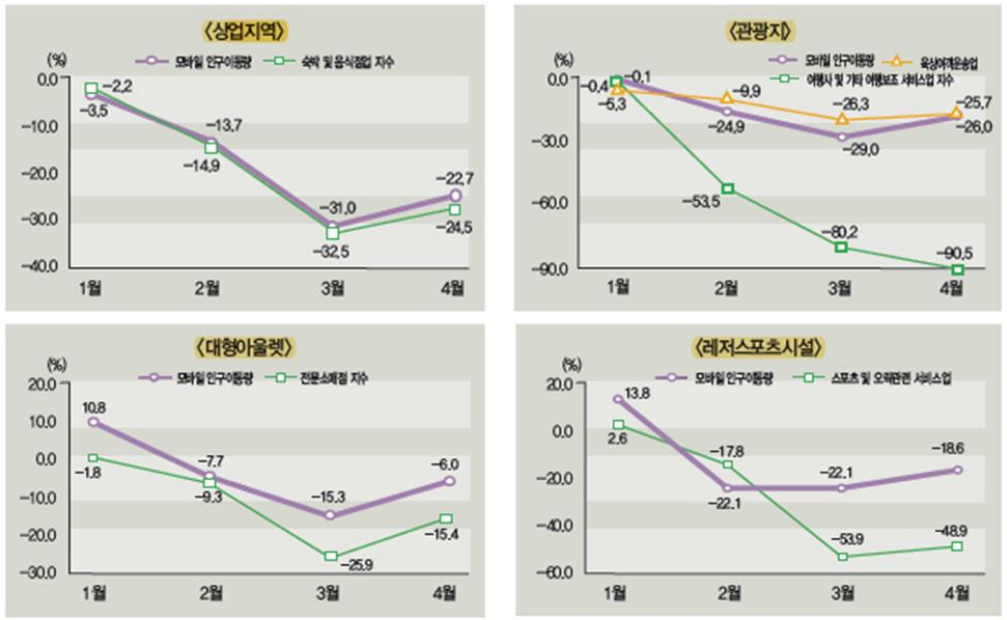


Source: Four Questions Telehealth Companies Must Answer To Ensure Long Term Growth, Joseph, Mar, 2021, Forbes.

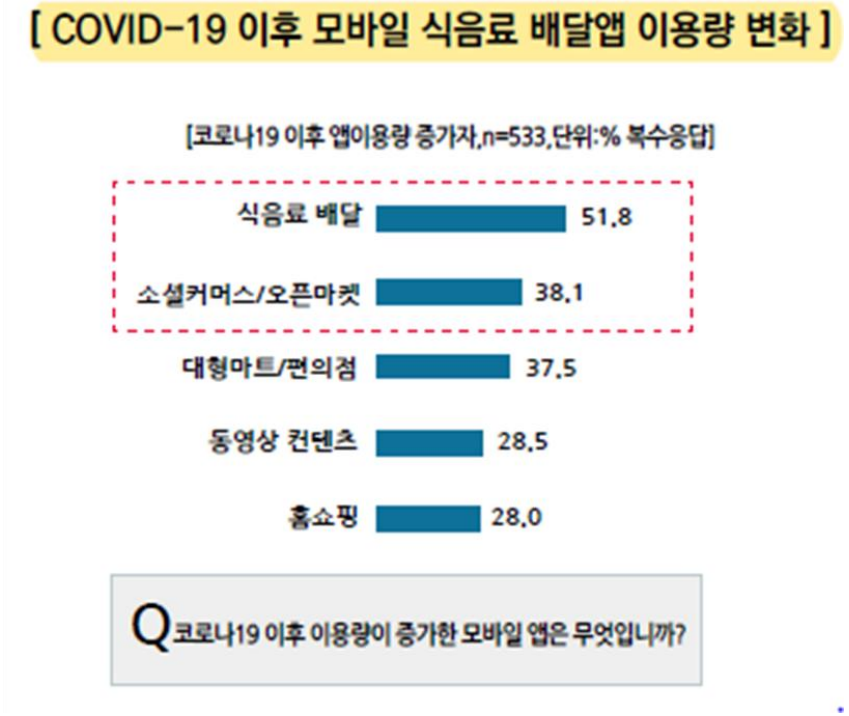
1.2. Environment change in Korea: COVID-19 Pandemic in Korea

Significantly reduced mobility and unhealthy eating habits → Affect Health Outcomes?

그림 8. 입지 유형별 인구 이동량 및 관련 업종 동향 추이(전년 동월 대비)



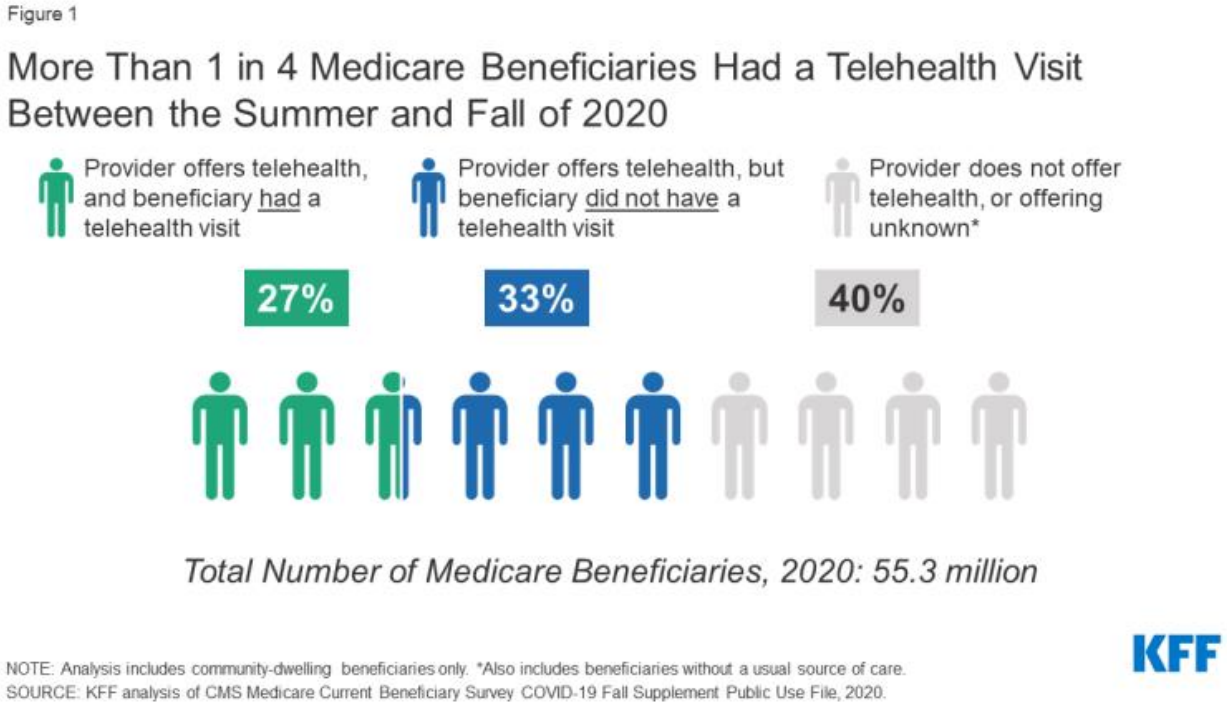
주: 서비스업생산지수 · 소매판매액지수는 불변지수
자료: 통계청 서비스업생산 및 소비 동향(2019~2020년), SKT 모바일 인구 이동량(2019~2020년)



1.2. Environment change in Korea: COVID-19 Pandemic in Korea

Since audio-only telehealth was allowed on February 2020, a total of 3.2 million cases were carried out at 16,950 clinics until August, 2021.

- **0.3% of the total number of outpatient prescription**
- **Internal Medicine 50.7% > General 8.5% > Neurology 7% > Psychiatry 5.5% > Family Medicine 4.5%**



Source: https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/

Introduction

The HCP perspective and next steps for the government

1 Background

2 Environmental change in Korea

3 Importance of Digital Adaptation

1.3. Importance of Digital Adaptation

It is a time when doctors need to adapt to the changing needs of their patients.

Due to COVID-19, patients hate long stays in hospitals. Therefore, it is impossible to operate an education program on the prevention and management of chronic diseases.

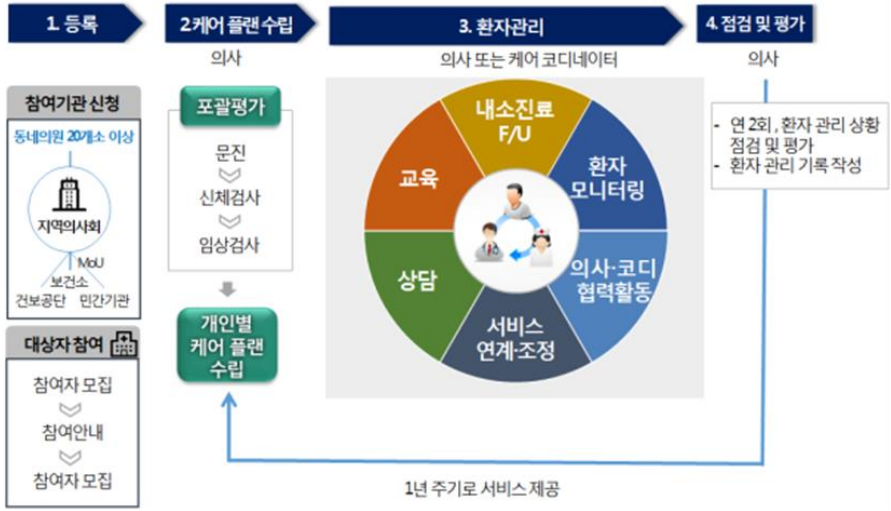
비의료 건강관리서비스 가이드라인 및 사례집(1차)

○ 만성질환자 대상 서비스 유의사항

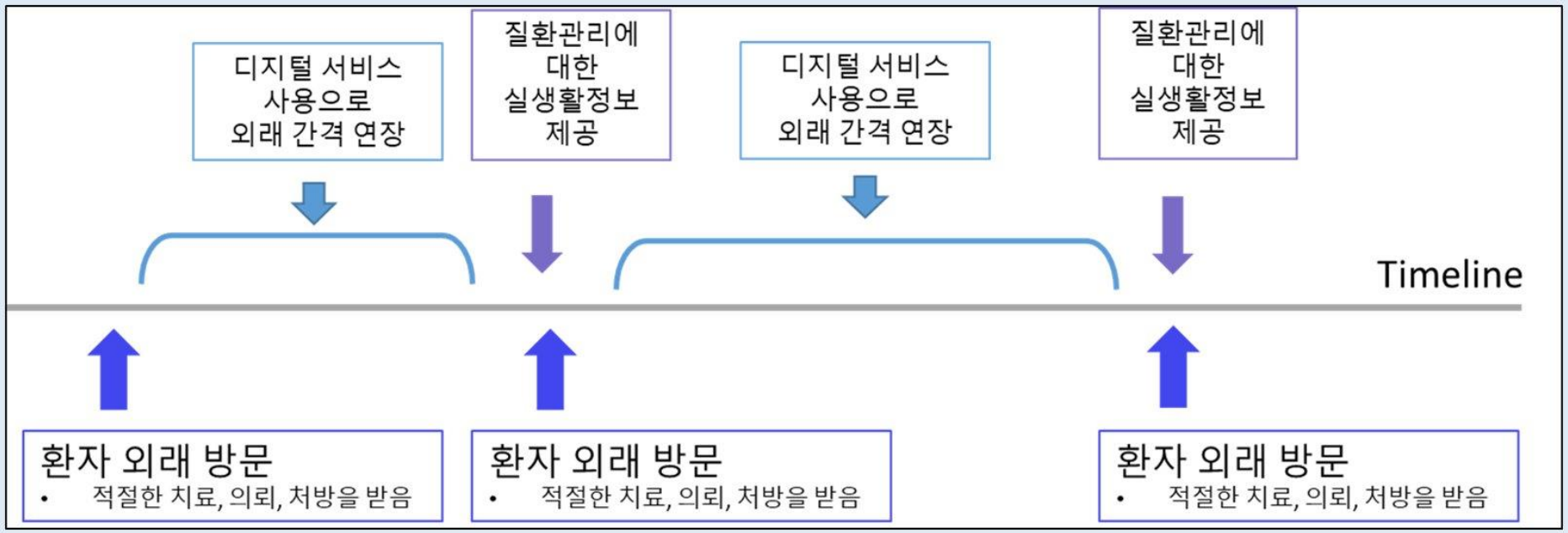
- 만성질환자에 대한 비의료적 상담·조언은 만성질환을 관리하는 목적으로 행해져야 함
- 특정 질환의 치료를 직접적 목적으로 하는 상담·조언은 '의료행위'성이 높으므로 의료기관에서 제공하여야 함
- 다만, 특정 질환의 치료를 위해 행하더라도, 비의료기관이 의료인의 판단·지도·감독·의뢰 하에서 행하는 경우 예외적 허용됨

일차의료 만성질환관리 시범사업

박 회장은 "코로나19로 인해 만관제 시범사업이 크게 다운돼 있다"며 " 만관제 시범사업은 상담이 중요한데, 환자들이 병원에 오래 있는 걸 싫어 한다



1.3. Importance of Digital Adaptation



Digital Intervention for HCPs

The HCP perspective and next steps for the government

1 Digital Therapeutics

2 Expectations of HCPs to DTx

3.1. Digital Therapeutics

PEAR THERAPEUTICS

Redefining Medicine

PRESCRIPTION DIGITAL THERAPEUTICS FOR THE TREATMENT OF SERIOUS DISEASE

3.1. Digital Therapeutics

Prevention

- Prevention of Alzheimer's dementia through cognitive rehabilitation training for patients with mild cognitive impairment
- Reducing the occurrence of schizophrenic symptoms through drug treatment and drug control for schizophrenia patients

Treatment

- Treatment of chronic insomnia through cognitive behavioral therapy for chronic insomnia patients
- Treatment of chronic major depressive disorder through psychological education and cognitive behavioral therapy for depression patients

Management

- Maintaining normal blood sugar by controlling the dosing according to the measured blood sugar for diabetic patients
- Manage side effects through monitoring nausea and pain in gastric cancer patients an d adjusting drug dosing

(출처: 디지털치료제 허가 심사 가이드라인, 식약처, 2020.)

Indications for Use:
reSET-O is intended to increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

Important Safety Information:
Warnings: reSET-O is intended for patients whose primary language is English and who have access to an Android/iOS tablet or smartphone. reSET-O is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications).

Please see additional Important Safety Information on back cover and accompanying Clinician Brief Summary Instructions on inside pages.

reSET-O™
ALWAYS ON HAND

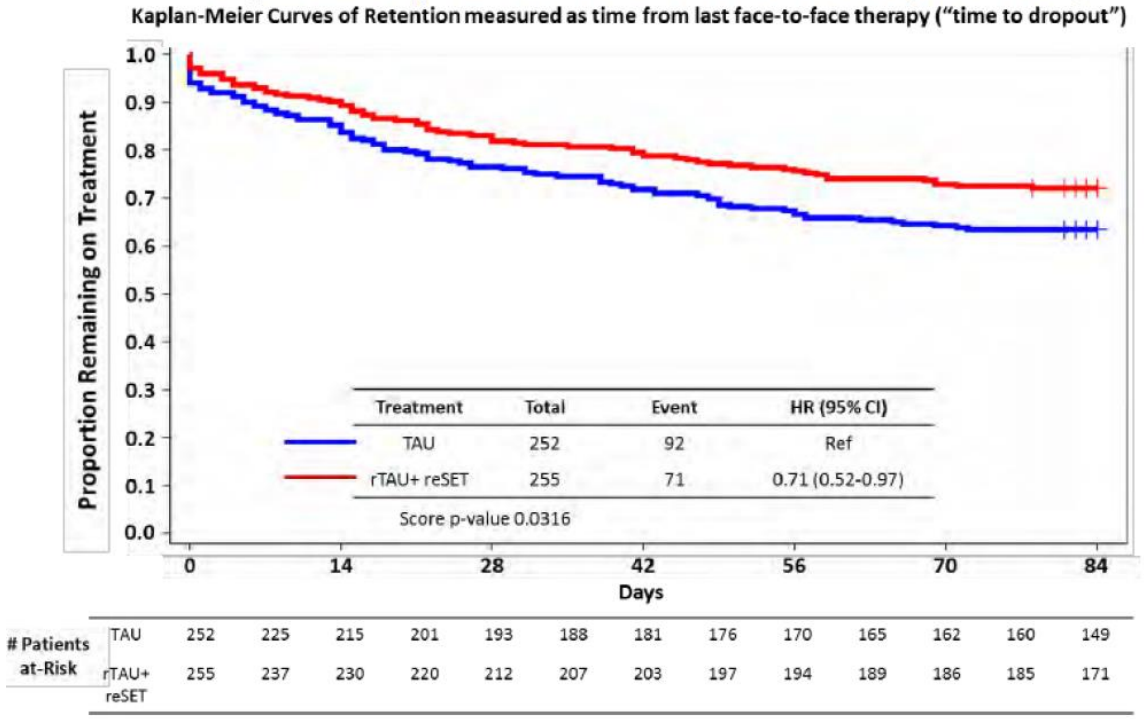
3.1. Digital Therapeutics

The first FDA-certified digital therapy, consisting of 62 sessions for therapeutic purposes related to addiction disorders

- 31 required sessions: life skills, treatment, emotional regulation, social restoration, sexuality, and prevention of infectious diseases → Learning and training at least twice a week → Providing incentives

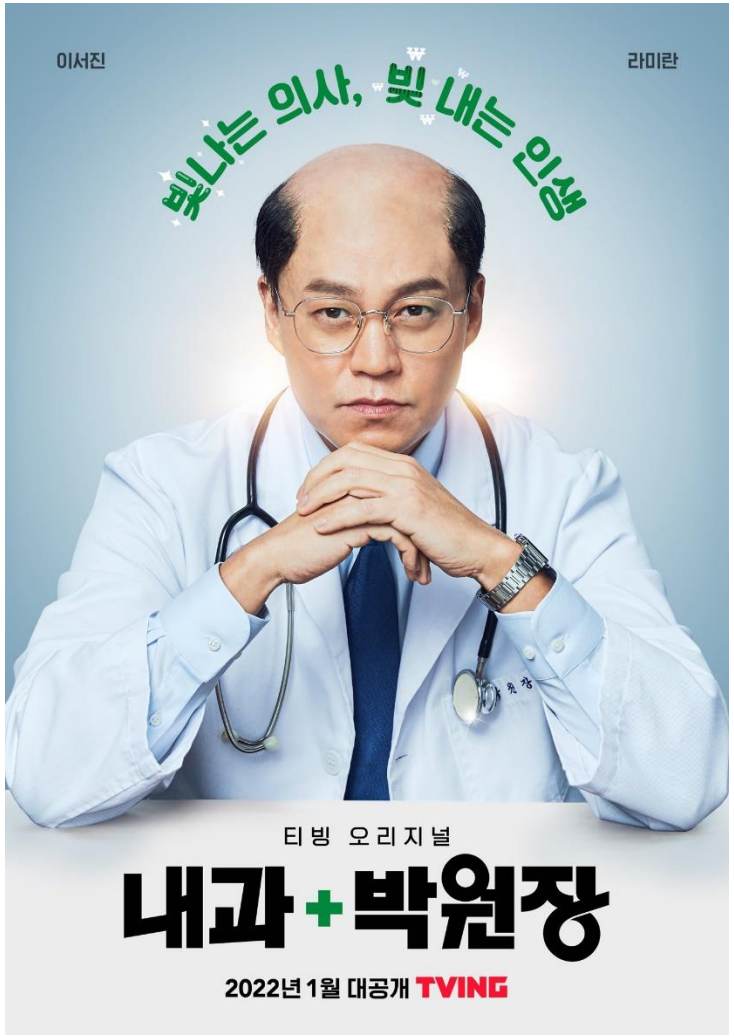
Probability of continuing to visit the clinics

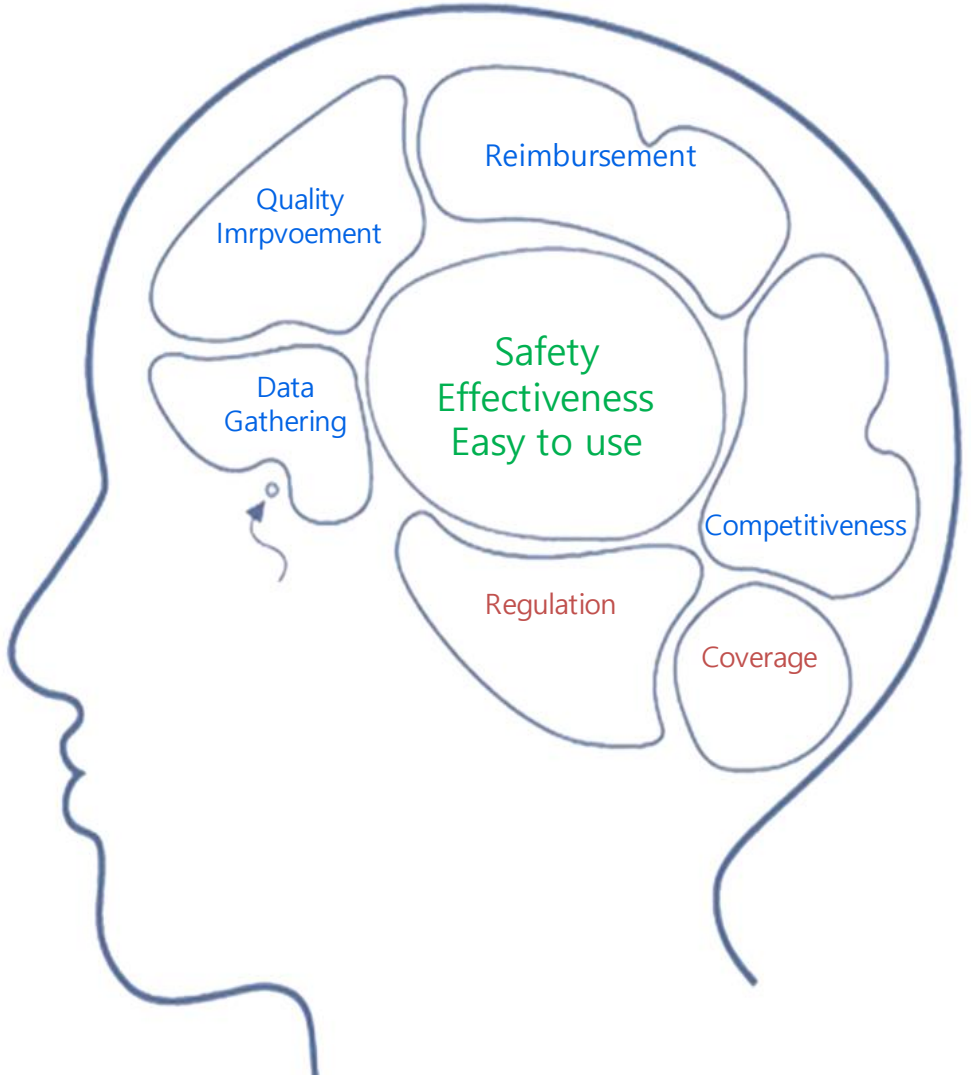
Figure 2: Kaplan-Meier curve for Cohort 1 (all comers)



3.2. HCPs' expectations and concerns about digital therapeutics

Prescribing Software? Not Medication?





Evaluating DTx for HCPs

The HCP perspective and next steps for the government

1. Mechanism of Action
2. Effectiveness of DTx
3. DTx-specific Real World Evidence

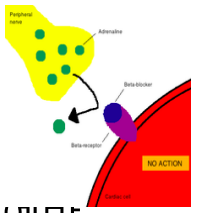
Requirements for being able to track and document the clinical improvement effect of software use

01

Mechanism of Action (MoA): standardized action of drugs

Specify in detail which parts and components of the intervention in software resulted in the expected clinical improvement

[당뇨 합병증 관리 DTx]
당뇨족(diabetic foot) 관리 체계적 교육법 제공 → 훈련 → 매일 당뇨족 관리 횟수 증가 → 입원 예방
→ ~~당뇨 식이 개선 → 당뇨 콩팥병 감소~~



02

Cognitive Behavioral Treatment and Real-world performance

- Cognitive behavioral therapy: thoughts, emotions, bodily sensations and final behavior are linked, and the vicious cycle caused by negative thoughts and emotions is blocked

3.1. Mechanism of Action

The importance of constructing cognitive behavioral therapy

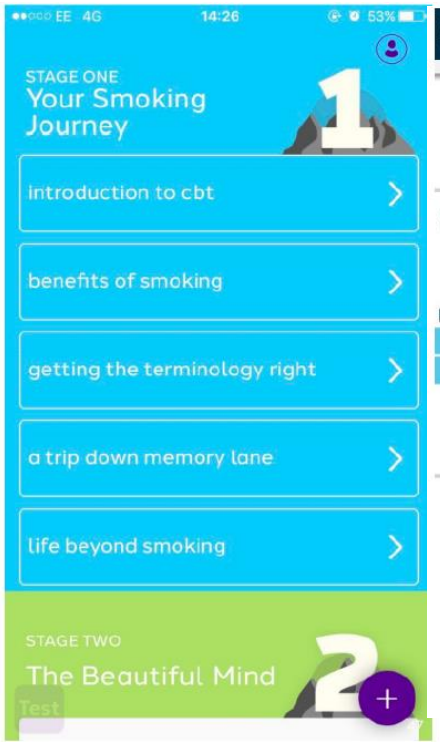


Table 3. Numbers of users whose willingness to use a smoking cessation app to manage their health was high, moderate, or low, for each ap
National Health Service.

Willingness to use smoking cessation app to manage health	Quit Genius (N)	NHS Smokefree (N)
High (increased willingness)	10	5
Moderate (no change in willingness)	4	4
Low (decreased willingness)	1	5

Table 4. Overall patterns of users' perceptions and health behavior change in relation to smoking cessation for each app.

Number of participants who:	Quit Genius, n (%)	NHS Smokefree, n (%)
Decreased number of cigarettes/day	8 (53)	2 (14)
Increased number of cigarettes/day	0 (0)	3 (21)
Showed increased motivation to quit smoking	8 (53)	5 (36)
Expressed desire to continue using app	10 (67)	5 (36)
Recommend the app	11 (73)	5 (36)

(출처: Eisingerich, et al., JMIR Mhealth Uhealth, 2018, vol. 6, iss. 4, e98, p. 1)

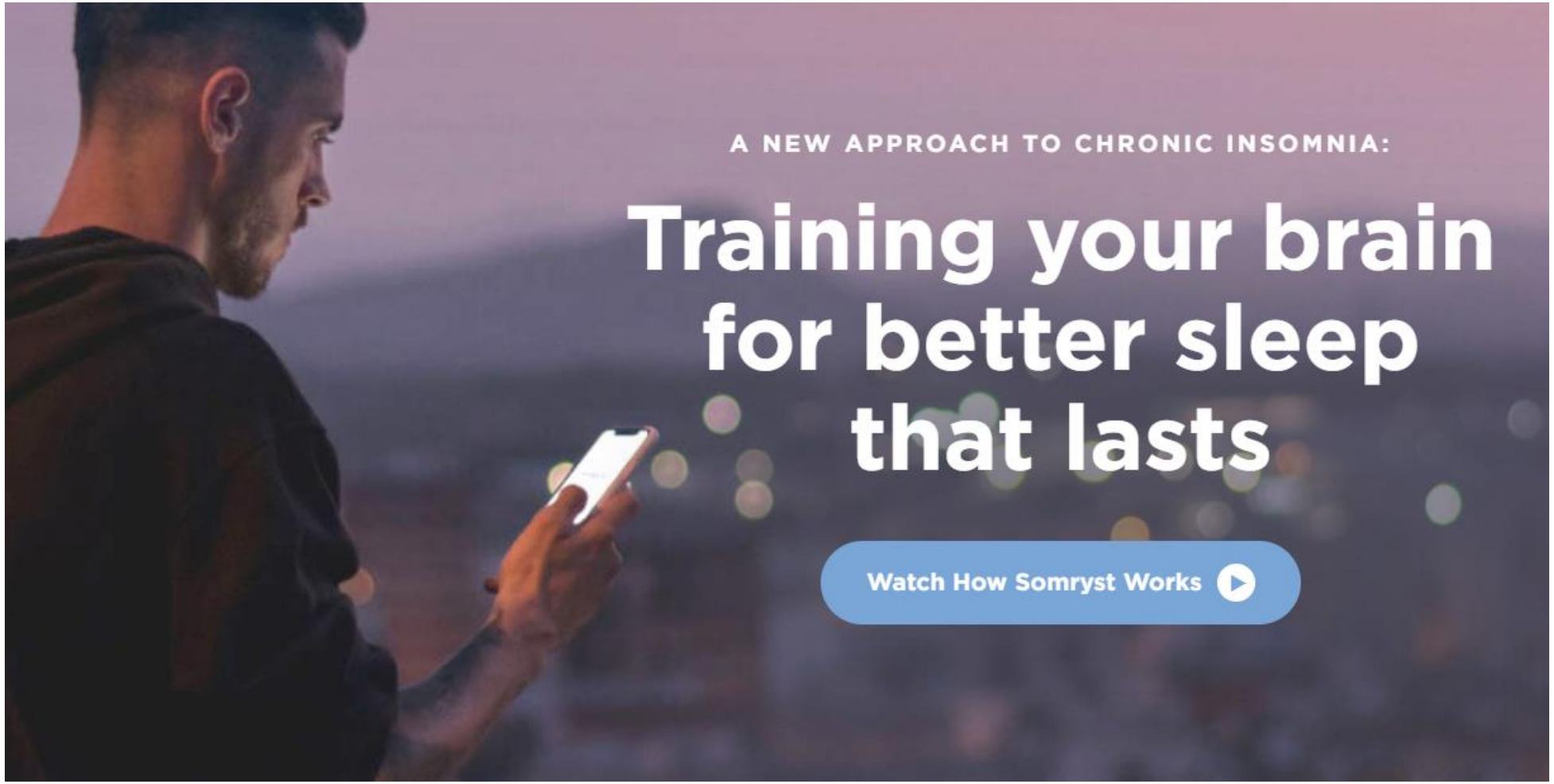
Evaluating DTx for HCPs

The HCP perspective and next steps for the government

1 Mechanism of Action

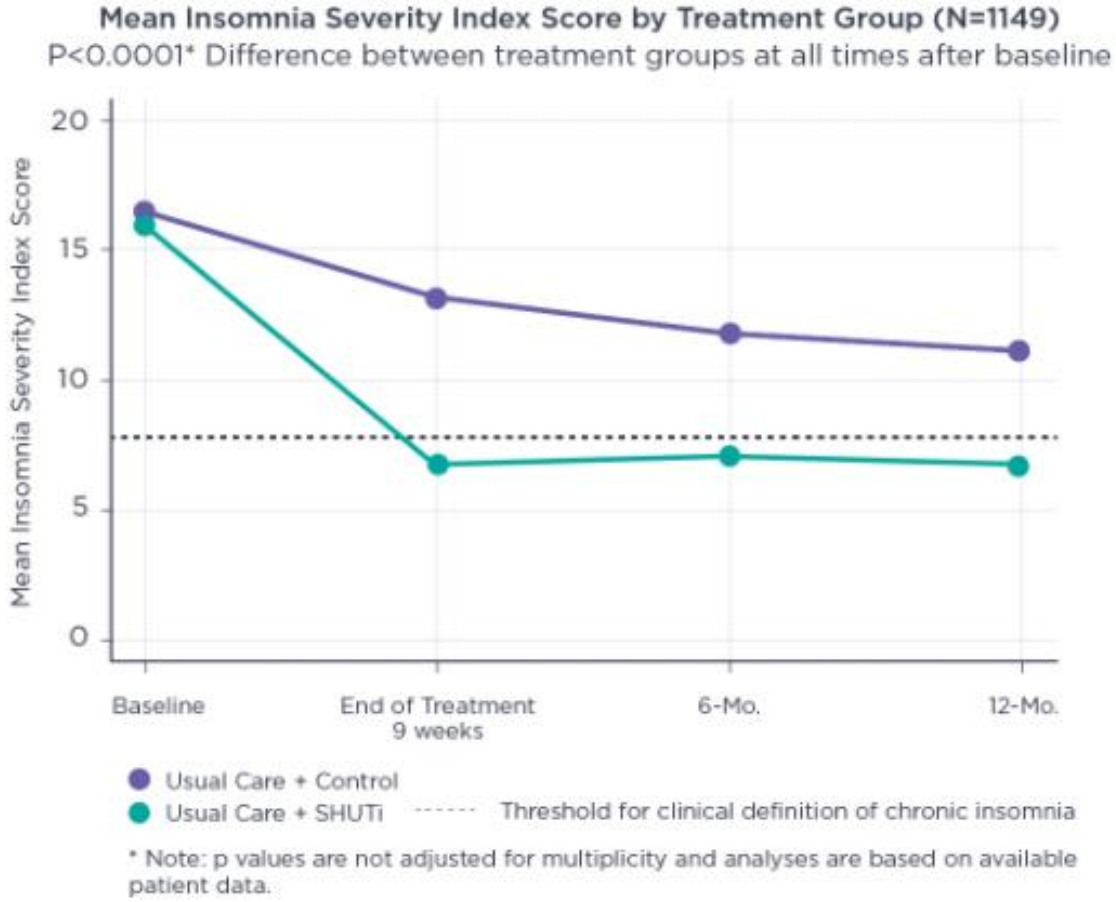
2 Effectiveness of DTx

3.2. Effectiveness: Somryst, PEAR Therapeutics



3.2. Effectiveness: Somryst, PEAR Therapeutics

Proven long-term maintenance effect after 6 weeks of use



(출처: Christensen H, Batterham PJ, Gosling JA, et al. Effectiveness of an online insomnia program (SHUTi) for prevention of depressive episodes (the GoodNight Study): a randomised controlled trial. Lancet Psychiatry 2016; 3: 333–41.)

Evaluating DTx for HCPs

The HCP perspective and next steps for the government

1. Mechanism of Action
2. Effectiveness of DTx
3. DTx-specific Real World Evidence

3.3. DTx-specific Real-world Evidence

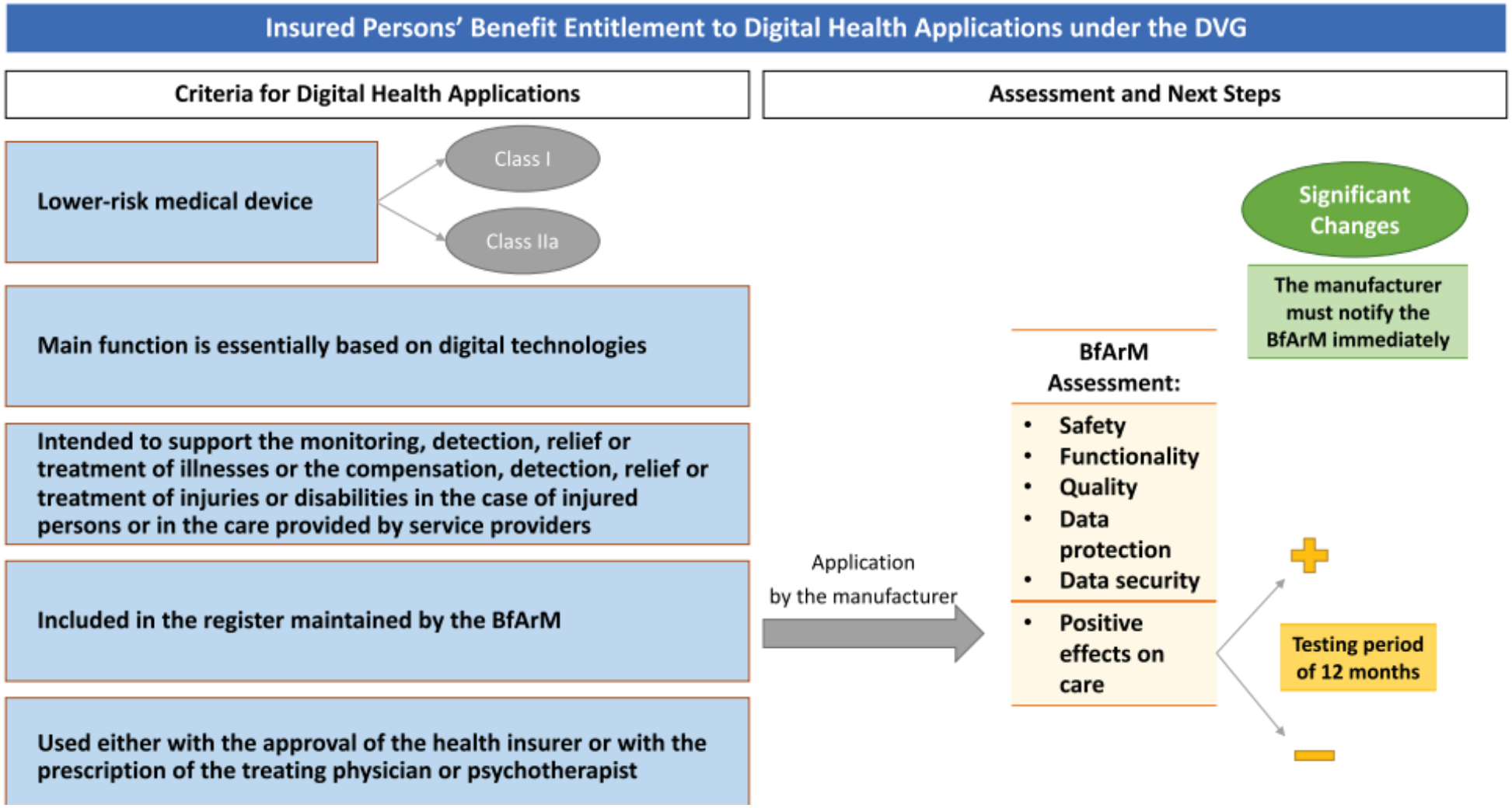
Fast-track based safety and effectiveness valuation for DTx

FDA's Pre-Cert RWE Domains and Items

Real-world Health Analysis	Real-world UI/UX Analysis	Program Performance Analysis
• Clinical Safety • Clinical Effectiveness	• Satisfaction • Participation • Communication	• Data Protection • Cyber security • Stability

3.3. DTx-specific Real-world Evidence: Digital Healthcare Act, Germany, 2020

Release first, Evaluate Later
- When satisfying five minimum criteria, Then providing reimbursement for 12 months -



3.3. DTx-specific Real-world Evidence: Digital Healthcare Act, Germany, 2020

A Comprehensive Approach to the Excellence of Digital Therapeutics

Accept it if it can add value to the health care system, even if it is not better than face-to-face

Medical Benefit

the improvement of the state of health

the reduction of the duration of a disease

the prolongation of survival

an improvement in the quality of life

Patient-relevant improvement of structure and processes

good and new possibilities for improving care

seen as part of the **detection, monitoring, treatment or alleviation of disease**

the detection, treatment, alleviation or compensation of injury or disability

aimed at supporting the health behaviour of patients or **integrating the processes between patients and healthcare providers**

3.3. DTx-specific Real-world Evidence: Digital Healthcare Act, Germany, 2020

Germany reached consensus on upfront payment for DTx of up to 2,000 Euros per year, Evidence Committee

Product	Indication	Date added	Hardware	Prices(Euro)
Invirto	Agoraphobia Panic	12/2020	VR, headphone	428.40
Kalmeda	Ringing in ears	09/2020		116.97
Somnio	Inorganic insomnia	10/2020	Fitbit (additional)	464
Velibra	Agoraphoniba	10/2020		476
Vivira	Back, knee, hip pain	10/2020		239.97
Zanadio	Obesity	10/2020		499.8
Elevida	Multiple sclerosis	12/2020		743.75
M-sense	Migraine	12/2020		219.99
Selfapy	Depression	12/2020		540
Deprexis	Depression	02/2021		297.50
Vorvida	Alcohol Use	05/2021		476
Hero	Smoking	0702021		239
Esysta	Diabetes	07/2027		249.86
Mika	OBGY cancer	02/2021		419

https://exitsandoutcomes.com/digital-health-reimbursed-in-germany-

Role and Responsibility of HCPs

The HCP perspective and next steps for the government

1 Maximizing relative value of DTx in healthcare

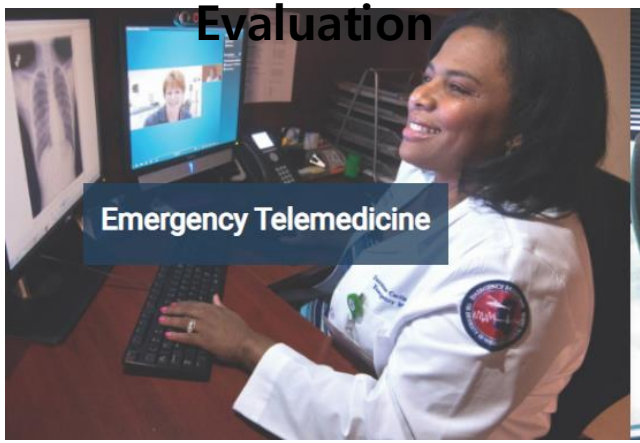
2 Role and Responsibility

5.1. Maximizing relative value of DTx in healthcare

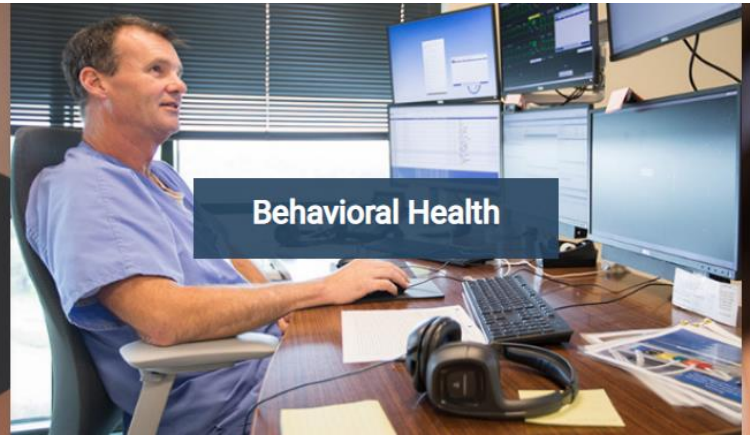
Through Rural Health Clinic certification in the United States, the number of all-inclusive rate concept is added

- Bundled payment of $100 per outpatient visit to the extent that much of it provides care and prevention
- The University of Mississippi Medical Center introduced tele-health specialized for rural health and innovative medical services, reducing glycated hemoglobin in diabetic patients by 1.7% (45% of mortality from heart disease), and no readmission within 3 months.
- Reports reduced Medicare financial penalties and reduced health care costs due to fewer emergency room visits

CDSS-based Trauma Evaluation



Sleep disorder (CBT-i)



VR-based DTx

5.2. The Role and Responsibility of HCPs

Should health care providers be charged for related services? If yes, what responsibilities and services do you provide?

Reimbursement for assessment

- Additional flat rate for issuing an initial prescription for DiGAV
- RBRVS, 18 → 2 Euros

Reimbursement for monitoring

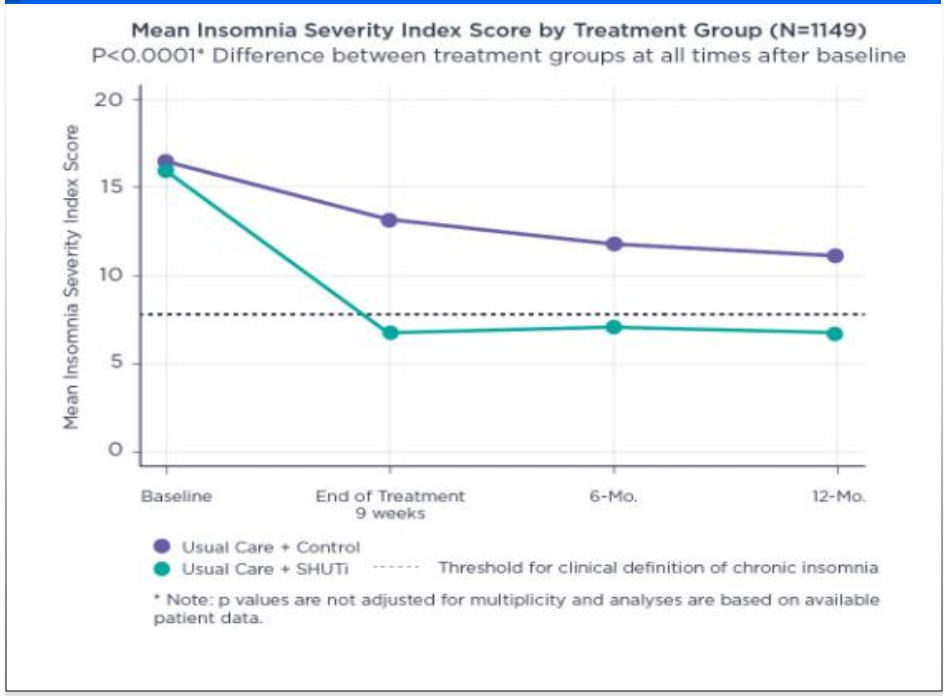
- Additional flat rate for the follow-up and the evaluation of the digital health application (DiGA) somnio
- RBRVS, 64 → 7.62 Euros

5.2.1. Monitoring for safety, efficacy and effectiveness

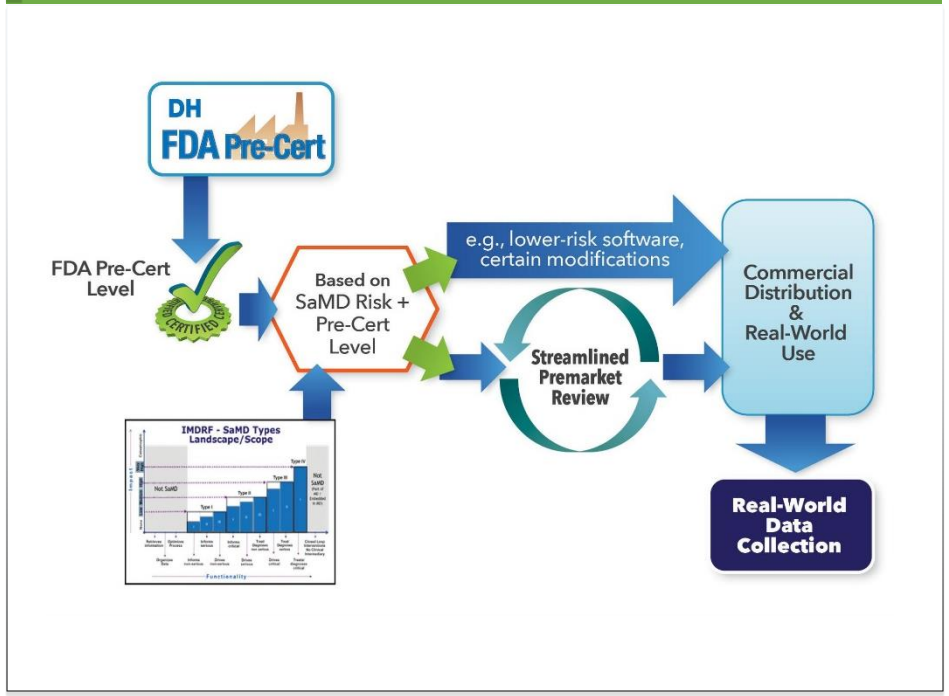
Digital treatment is differentiated from existing wellness programs as prescribed digital medications

- **(Safety, Social Responsibilities)** Does DTx show sufficient safety to treat people's diseases?
- **(Efficacy, professionalism)** Does DTx show sufficient efficacy as stated?
- **(Efficiency, manager)** Does the digital treatment show positive efficiency in the management of clinics and the finances of health insurance?

Somryst 의 단기 중재 이후, 장기 유지 효과



Pre-Cert 내 DTx Real-World Evidence 컨셉



5.2.2. Assess potential risks to HCPs

Establish a compensation system for cost-effective treatment without increasing the workload of existing doctors

Stakeholder	Benefits, Risks, and Distractions	Recommendations
Hospital systems, ACOs and IDNs	- Providers with large purchasing departments can help spur adoption of DTx - DTx solutions must not add overhead or create more work for physicians or health system stakeholders	- Ensure co-development of DTx solutions with health systems - Optimize DTx for integration with existing health system workflows - Organize forums and provide literature to ensure medical teams and patients understand DTx treatment options

(출처: How Digital Therapeutics Developers Can Satisfy Diverse Stakeholder Needs, Syneos Health, 2020)

감사합니다

drshin@yuhs.ac/

js3483@cornell.edu

Jaeeun Myung, MPharm, PhD candidate
Health Economics & Data Analyst
@Medtronic Korea

Industry position

The APACMed Policy Paper

APACMed Approach

Analysis of the current approaches to gain reimbursement

Interview of key policy and provider stakeholders across the APAC region

Creation of 2 country-archetypes to consolidate DHT best practices and guiding principles

- **Australia:** developed market from health coverage and DH perspectives
- **India:** developing country with a mixed payer model and at the earlier stages of DH blueprinting

※ APACMed is currently organizing closed-door dialogues with key Australian stakeholders

APACMed Policy Recommendations

1 Step 1 — *Situational Analysis*

- Establish a DHT-specific categorization that is in line with international standards
- Framing the potential opportunity for DHT impact
- Map to healthcare archetypes

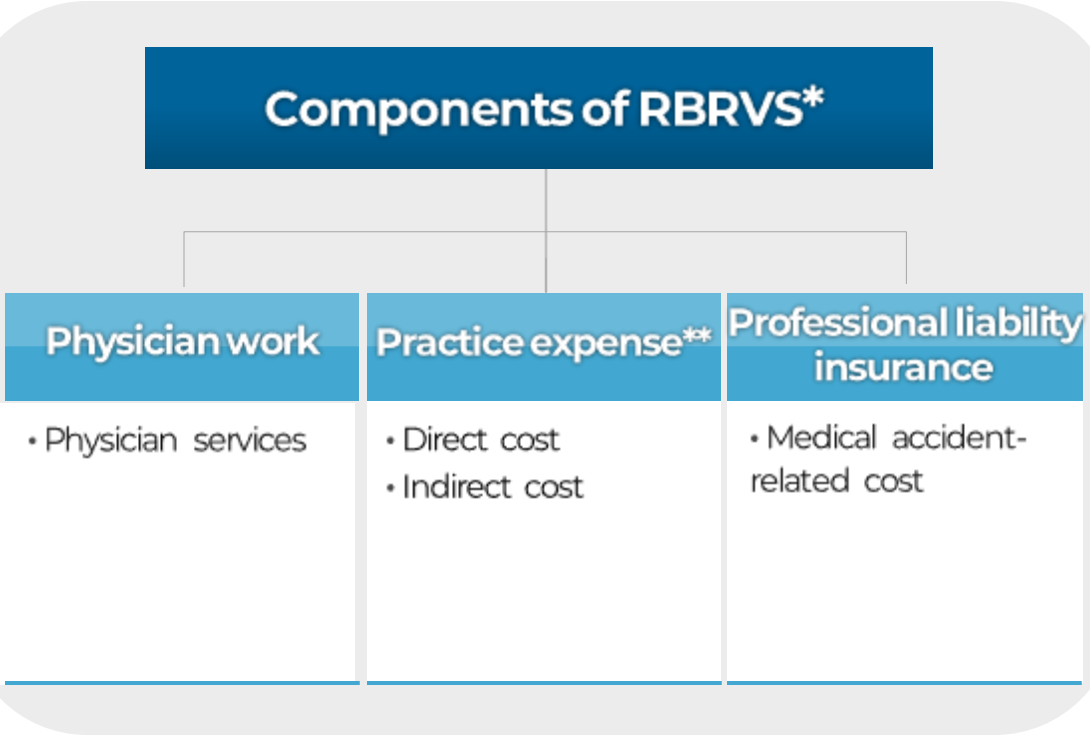
2 Step 2 — *Planning*

- Incorporate DHT into national planning cycles
- Create a multi-stakeholder taskforce
- Identify local champions who can serve as role models in ushering in the wave of DHT reimbursement & funding models

3 Step 3 — *Execution and Adoption*

- Publish a clear roadmap to achieve DH funding and reimbursement
- Ensure the right workforce capability levels, skills, capacities, training for DHT
- Implement monitoring processes

What Issues We Have in Korea?



* **RBRVS:** Resource-Based Relative Value Scale

** **Direct cost:** non-physician clinical labor, disposable medical supplies, medical equipment

Indirect cost: administration, rent, other overhead

DTHs mostly contributes reduced physician work and labor cost…

Does current RBRVS reflects the value and costs of DHTs?

Case 1. Long-term continuous electrocardiography (ECG)
Within 48 hours (E6545; *existing code*; KRW 55,789)
48 hours – 7 days (E6556;KRW 148,686)
7 days – 14 days (E6557; KRW 203,139)

Case 2. Gait training care using robots in stroke patients
Gait Training (MM302; *existing code*; KRW 18,083)
+ extra robot usage (MM304; KRW 32,397)

**Amount based in tertiary teaching hospital*

APACMed Policy Recommendations

Proposed Value Assessment Framework for DHTs

Safety and Clinical Effectiveness
The evaluation of safety and clinical effectiveness should be more flexible than that of traditional MD

Economic impact
An analysis of the costs for integrating the DHTs into the healthcare system should be conducted

Patient and Social Aspects
The overall patient experience should be measured by speed, convenience, access and patient empowerment

Organizational Aspects
Health systems should be prepared for the adoption of DHTs for instance through the training of HCPs

Usability
The support provided by the DHTs for the patient should be evaluated using user experience standards

Technical Aspects
Their evaluation should mainly consider infrastructure requirements

Interoperability
Connectivity of DHTs to other data sources to achieve an integrated healthcare system should be evaluated

Data security
Ethical data acquisition and strict data security standards should be evaluated

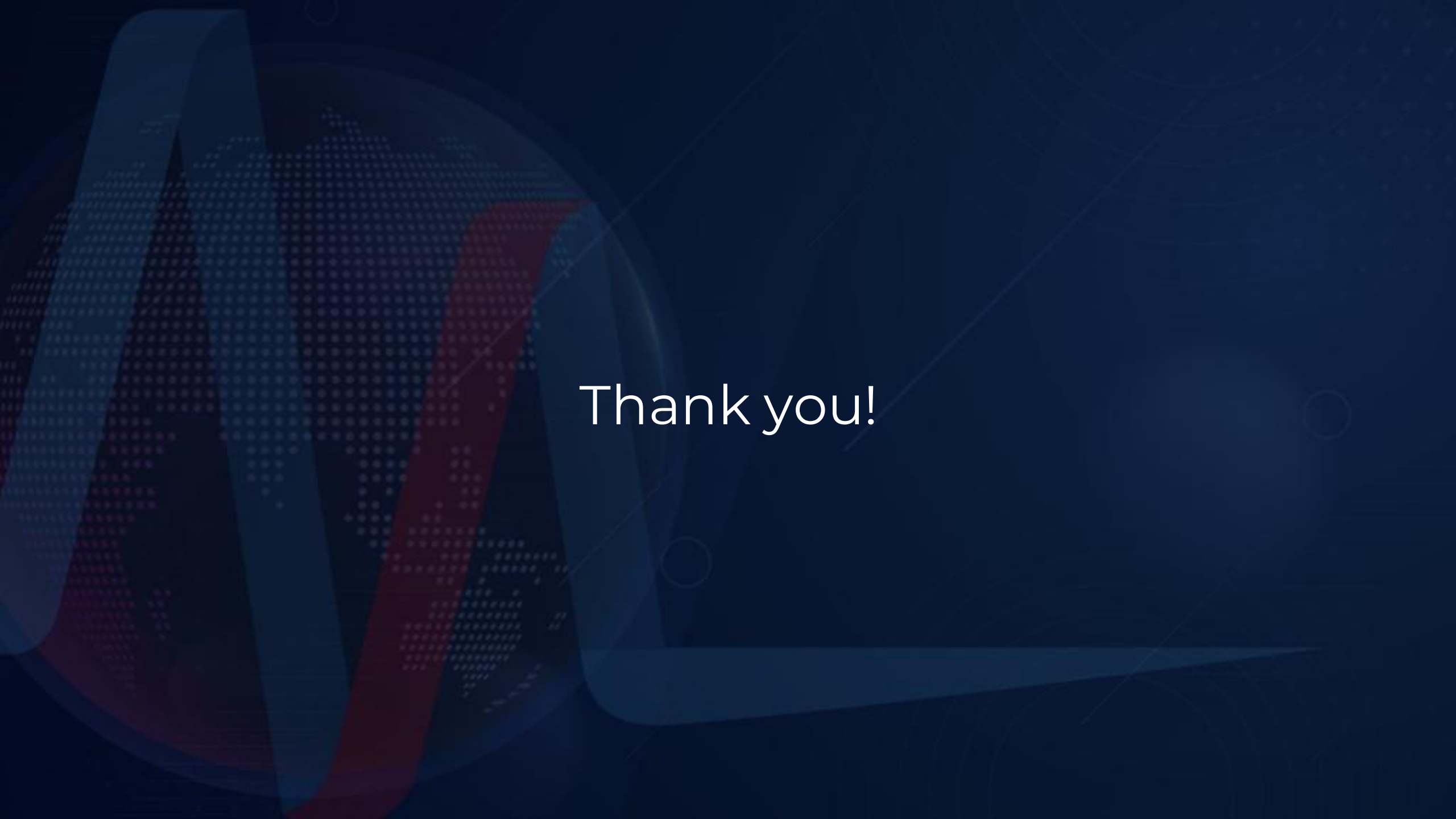
MD medical device; DHTs digital health technologies

Closing remarks

In 2022, APACMed and KMDIA will **drive country activation initiatives in Korea**, and in particular:

- Strengthen our collaborations with local stakeholders and policymakers, to support them to develop reimbursement frameworks for digital health
- While continuing to support the industry to build their capabilities

We will also continue working in other Asian countries.


Thank you!