

디지털 치료제를 활용한 정신건강관리

웰트(주) 대표이사
연세대학교 예방의학교실 외래교수
대한디지털치료학회 산학협력이사
한국의료기기산업협회 이사

강 성 지 MD, MPH



얼마를 받아야 할까?



모바일 정신 건강 치료용 ...
bosa.co.kr



신체건강 넘어 정신건강 관리까지 넘...
nocutnews.co.kr



정신건강 앱으로 마음 방...
donga.com



정신건강 자가검진 어플 - 마음건강로드맵(수원시행복...
youtube.com



정신 건강 치료용 앱 '마나' ...
khanews.com



셀프심리치료 할 수 있는 앱 '카잉블루' 곧 공개 < 의로기...
moneys.co.kr



내 손 안의 정신건강 전문의
m.health.chosun.com



후생신보 | 세종충남대병원 정신건강의학과 조철현 교수, ...
whosaeng.com



우울증 정신건강 관리 ...
yamlove77.com



정신건강 진단하는 앱, ...
mediawhy.com



코로나로 건강 앱 인기...영상 앱 등 정신건강 ...
medicalreport.kr



우울하세요?...셀프진단 ...
yna.co.kr



보건복지부 국립정신건강센터...
ko-kr.facebook.com



온니씨앤에스, 공감 인공지능 정신...
m.medicaltimes.com



비대면 건강 어플
mk.co.kr



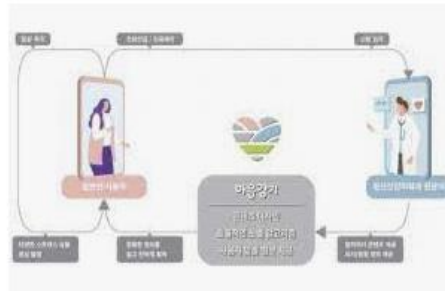
정신건강 앱으로 마음 방역 하겠다* : 뉴스 : 동아...
donga.com



코끼리 명상앱, 10월 세계 정신건강의 달 '너'...
sedaily.com



몸 건강, 마음 건강 토탈케어! 웰스케어 ...
kyobolifeblog.co.kr



앱을 통해 정신과 전문의 소개..정신건강 플랫폼 '마'...
mindpost.or.kr



언제 어디서나 스마트하...
m.blog.naver.com



메디포뉴스
medifonews.com

약이란 무엇인가?

아스피린 원료 → 버드나무 추출물

안전성 유효성

규격화 글로벌화

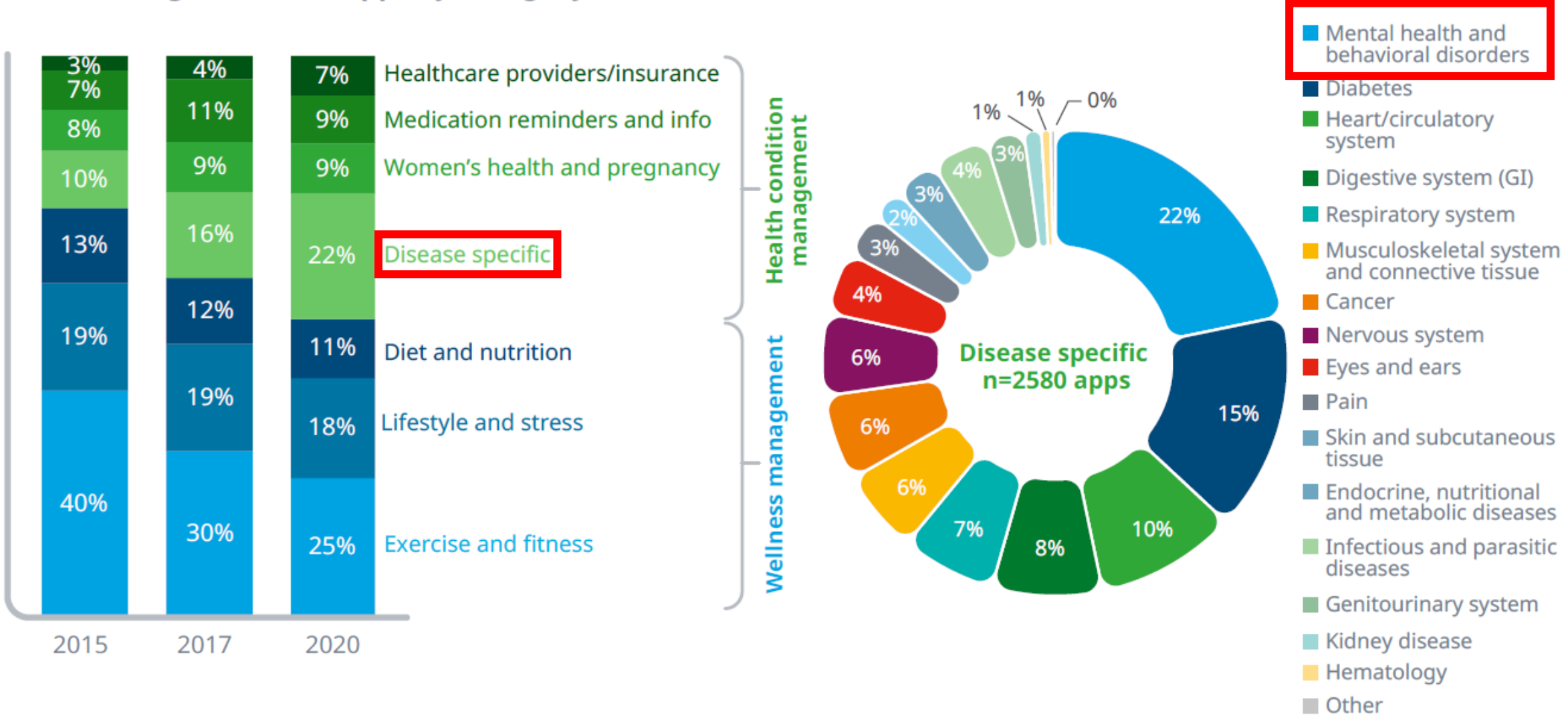
표준화 산업화

버드나무 추출물

소프트웨어를 관리하는 방법?

1. 누구를 믿어야할까?  식품의약품안전처
2. 어떻게 관리해야할까? **제품에 맞춰서**
3. 얼마를 받아야 하나? **효과에 따라서**

Exhibit 5: Digital Health Apps by Category and Disease State in 2021



Source: 42 Matters, Jun 2021 and Jul 2017; Mevvy, Jun 2015; IQVIA AppScript App Database, Jun 2021; IQVIA Institute, Jun 2021

Notes: Chart displays percent of categorizations. Numbers may not sum due to rounding; 2020 data includes 11,543 unique apps with 11,569 categorizations. 2017 data includes 11,216 unique apps with 11,249 categorizations. 2015 data includes 24,012 apps with 24,088 categorizations. 2020 view removes apps pending review.

Regulatory Framework for Digital Therapeutics in APAC

										
	US	EU	S. Korea	Japan	China	Taiwan	India	Indonesia	Singapore	Australia
Regulatory Agency	FDA	European Commission	MFDS	PMDA	NMPA	TFDA	CDSO	NADFC	HSA	TGA
DTx Regulation	Class II 510(k) or De Novo	Class IIa, IIb	Class II	Mostly Class II	Class II	Class II	Class C	Class C	Class B	Class IIa, IIb
Pre-submission	Yes	No	Emerging	Yes	No	No	No	No	Yes	Yes
Approval Timeline	9-12 months	2 years	6-8 months	12 months	6 months	10-12 months	6-9 months	4 months	3-4 months	4-6 months
Alternate Pathways	Wellness, Exempt, Enforcement Discretion	Class I	Class I	Exempt	Class I	Consumer Health	Consumer Health	Consumer Health	Class A (exempt)	Excluded, Class I
DTx Clinical Data Requirements	Sham-controlled RCT generally required	RCT generally required	RCT generally required	RCT generally required for novel devices	Clinical evaluation required; RCT may be required	Clinical data generally required	Clinical data generally required	Clinical data generally required	Clinical data generally required	Clinical data generally required; RCT for novel devices
Clinical Data Portability	Must be relevant to US demographics and SOC; Must follow GCP	Must demonstrate state of the art; Must follow GCP	Foreign clinical data may be accepted if relevant to Korean population	Clinical data must be obtained on Japanese population	Foreign clinical data can support local data	US and EU clinical data accepted	Foreign clinical data accepted	Foreign clinical data accepted	US, EU, Canada, Japan, Australia clinical data may be accepted	US, EU, Canada, Japan, Singapore clinical data may be accepted
Government Reimbursement	Limited / emerging; additional data typically required	Yes / emerging depending on market; additional data required	Emerging	Yes; Same data may potentially be used	No	No	No	No	No	Emerging; depends on therapeutic area
International Standards										
IMDRF Framework	✓	✓	✓	✓	✓		✓		✓	✓
IEC 62304 - SDLC	✓	✓	✓	✓	✓		✓			✓
ISO 13485 - QMS		✓	✓	✓	✓	✓	✓	✓		✓
ISO 14971 – Risk Management	✓	✓	✓	✓			✓			✓

불면증

알코올 중독

마약중독

우울증

ADHD

PTSD

불안장애

공황장애

편두통

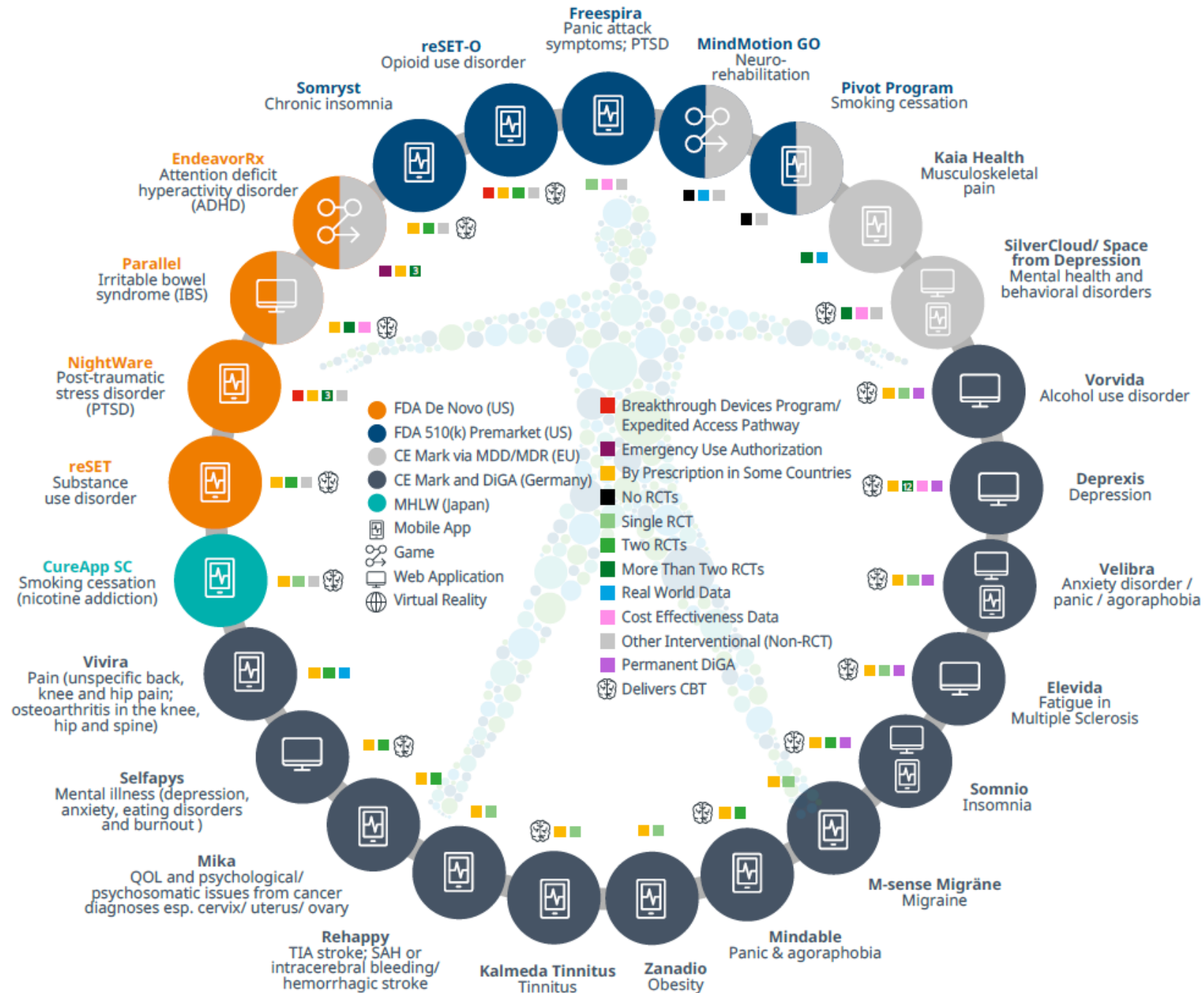
이명

비만

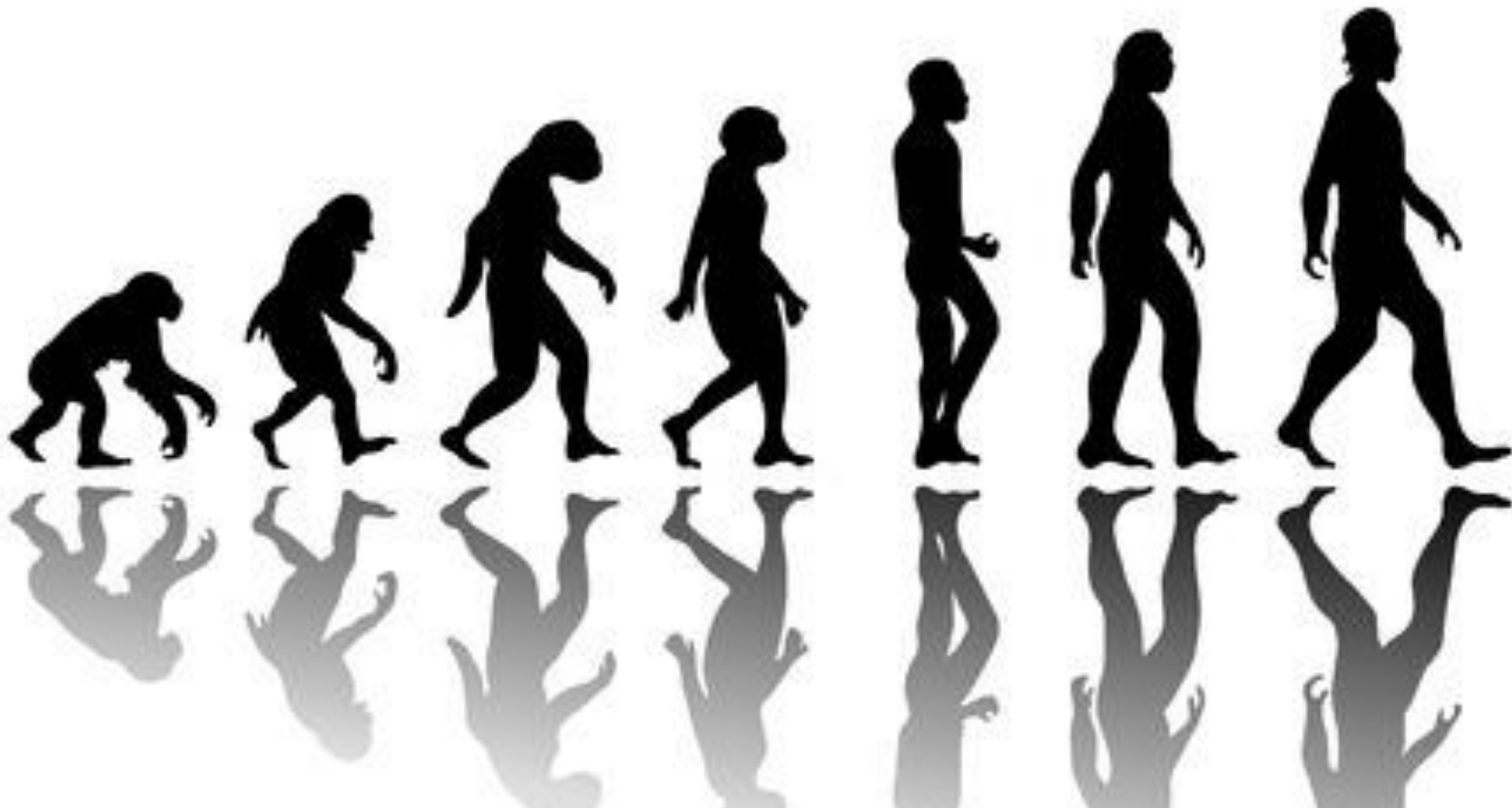
금연

섭식장애

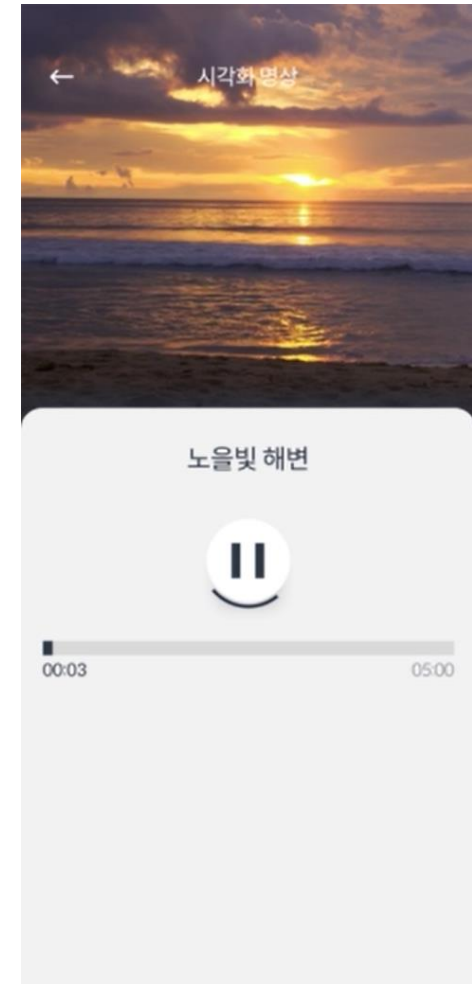
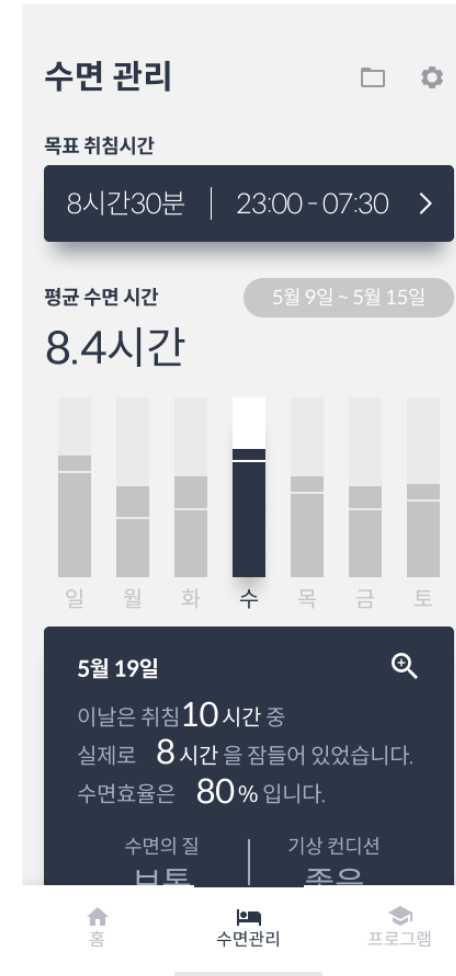
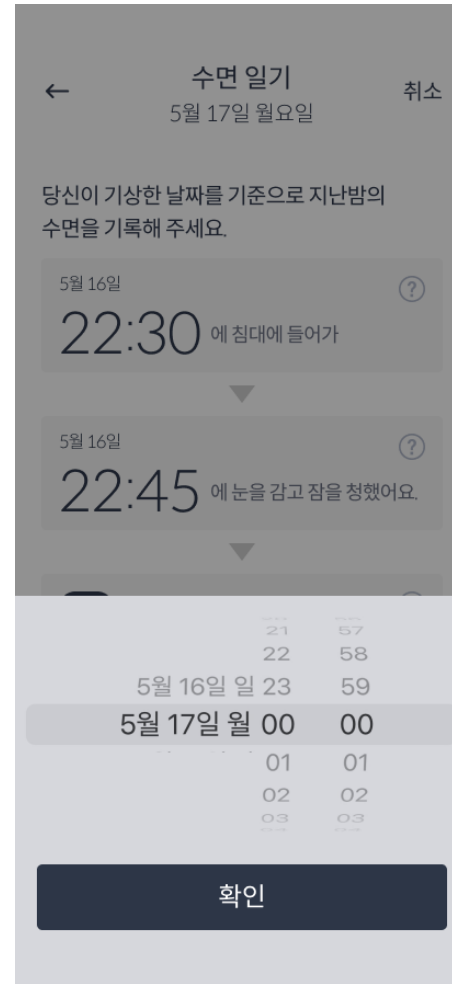
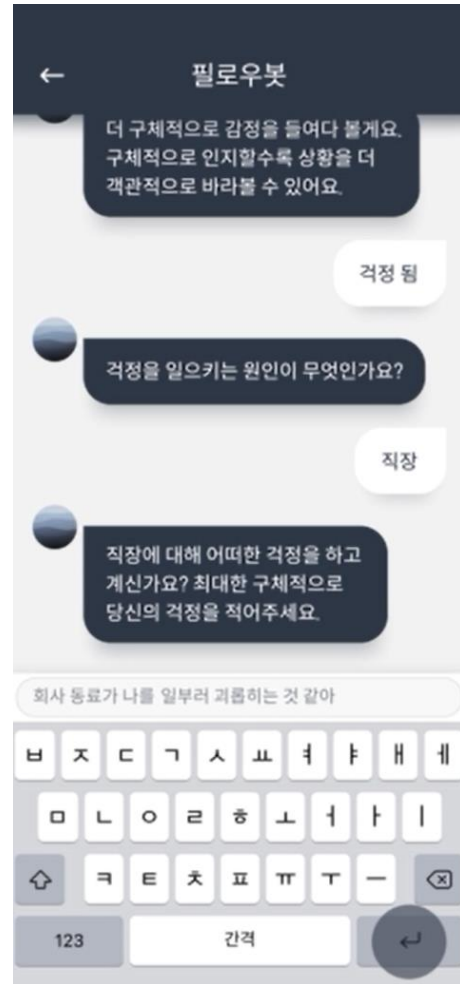
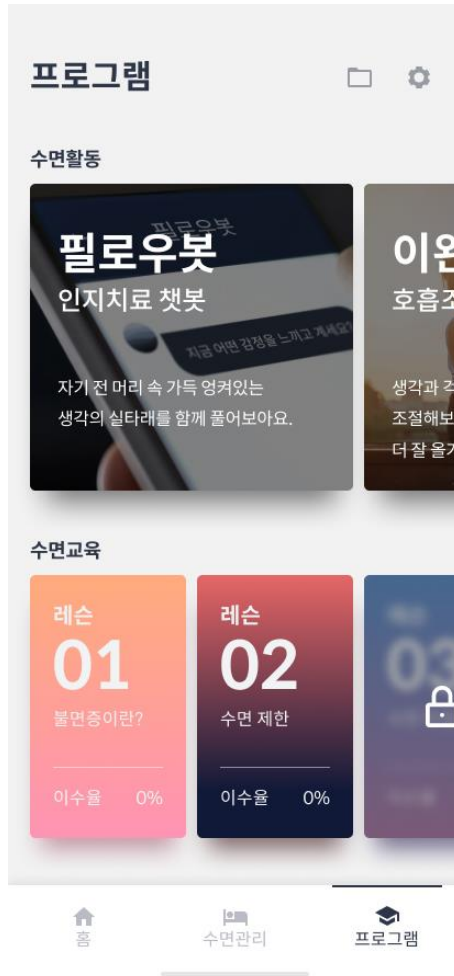
과민성 대장증후군



소프트웨어 의료기기 = 진화하는 의료기기

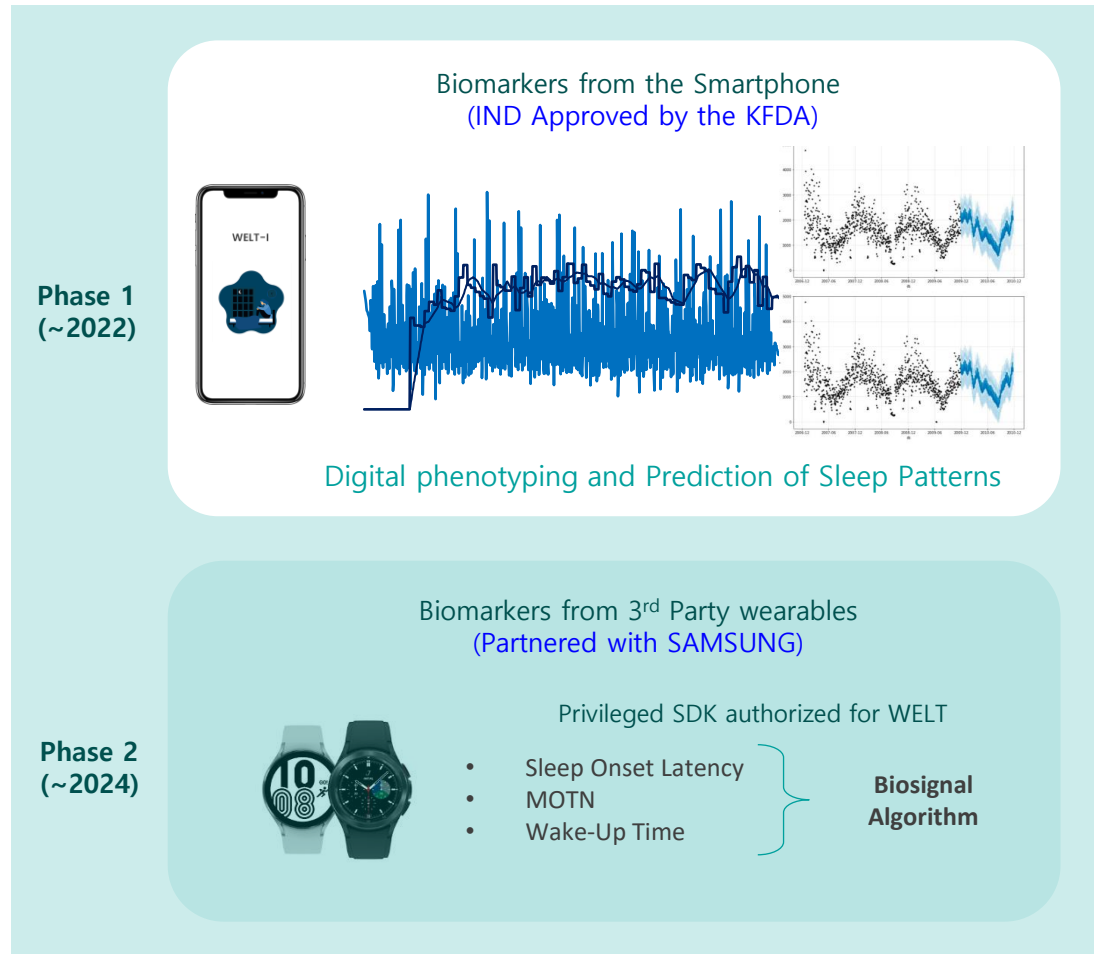


PILlow Rx – ver 1.0



PILlow Rx – ver 2.0

AI-powered symptom monitoring



← Sleep Diary Monday, May 17th Cancel

Please record last night's sleep.

May 16th
I got into bed at 23:00

May 16th
I tried to go to sleep at 23:10

I could not sleep at all ☐

Took me to fall asleep 0h 00m

1/5

Next

SLEEP

Time-in-Bed Goal
6 hrs 30 min | 23:30 - 06:00 >

Average Sleep Time May 09 - May 15
7.5 hrs

S M T W T F S

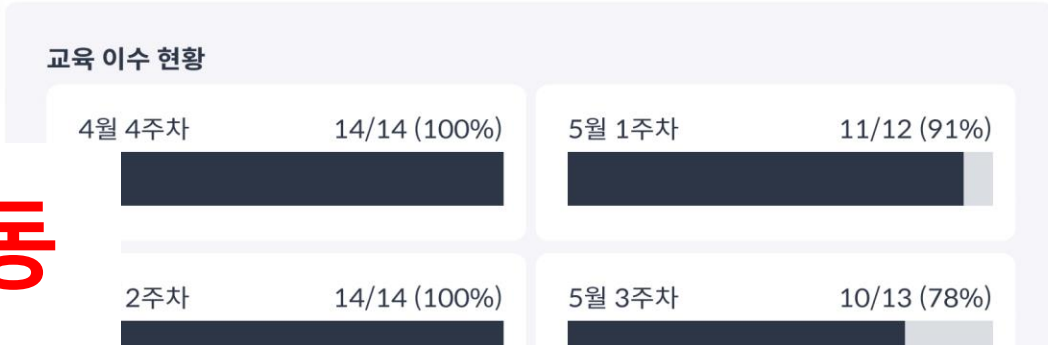
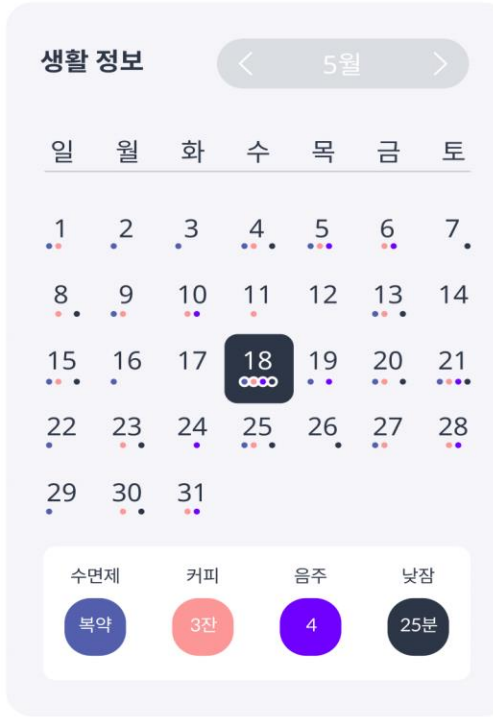
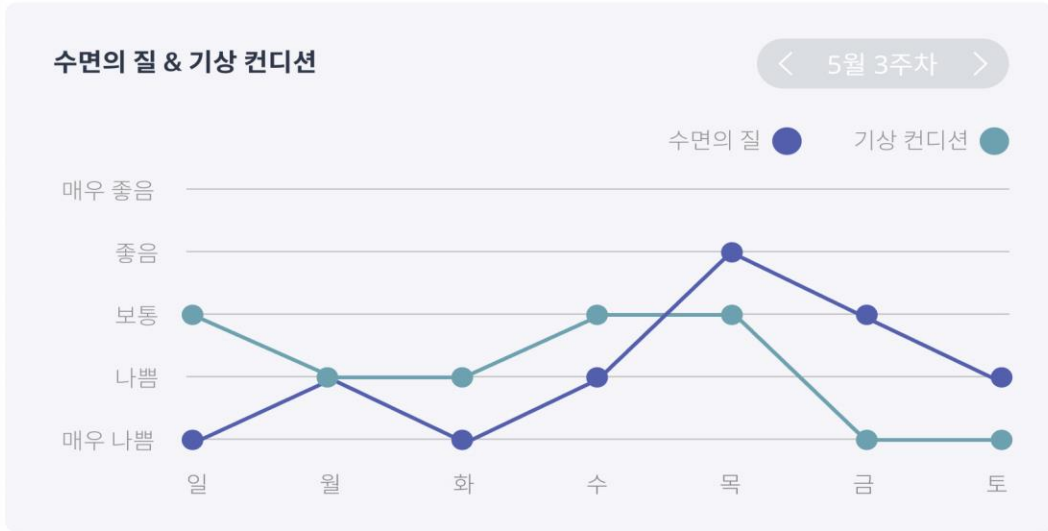
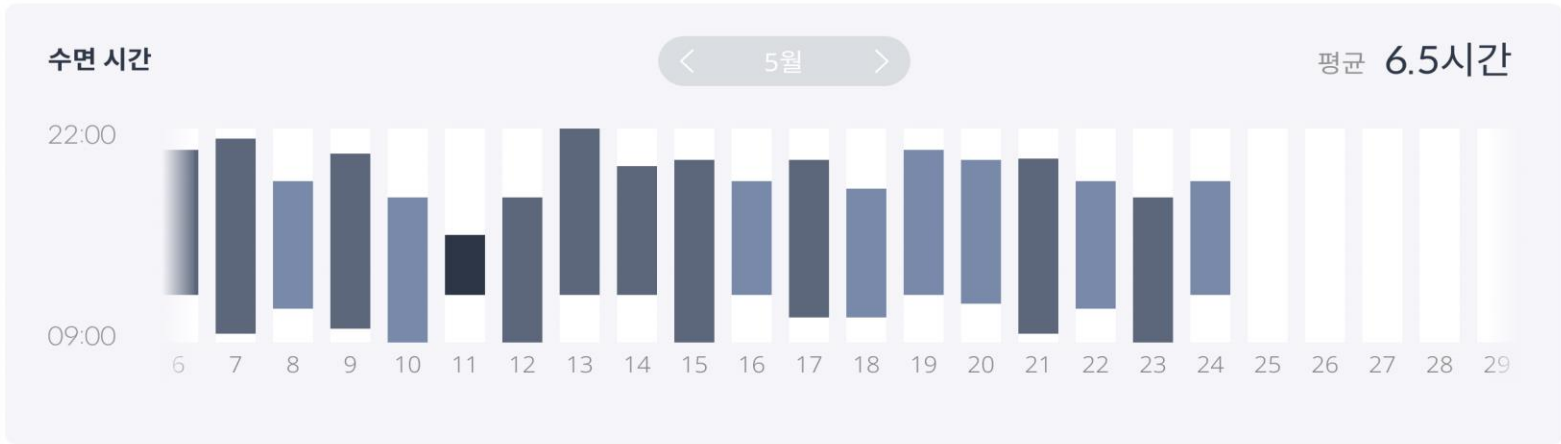
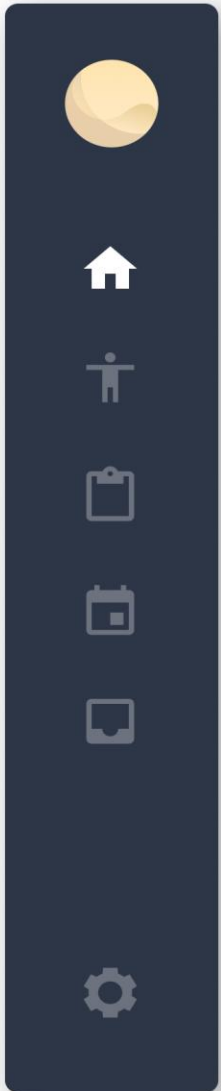
May 15th

You spent 9 hrs 15 min in bed and slept 4 hrs 32 min.
Your sleep efficiency was 49%.

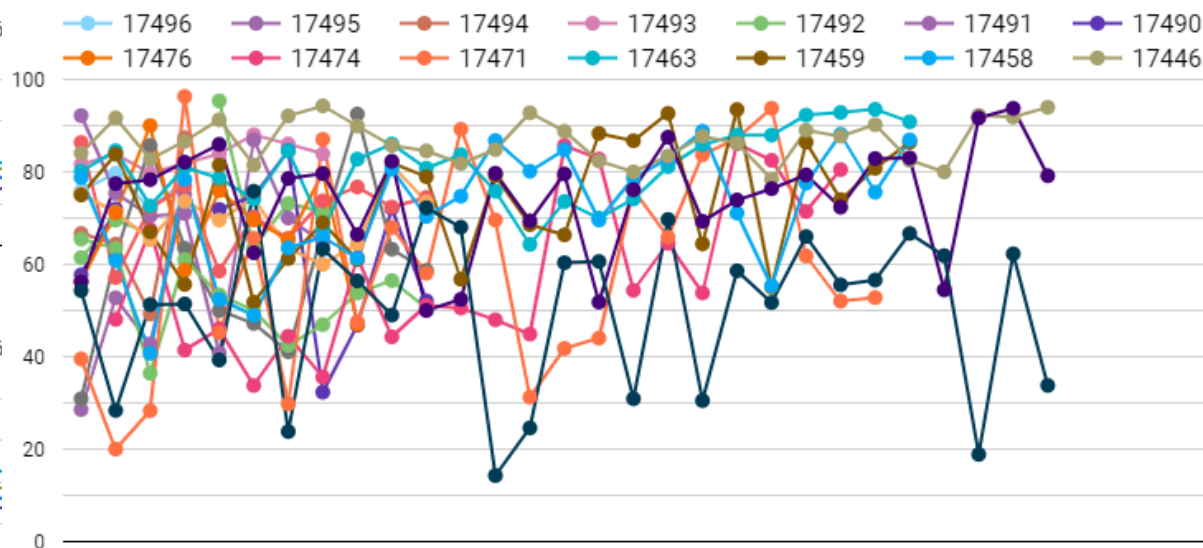
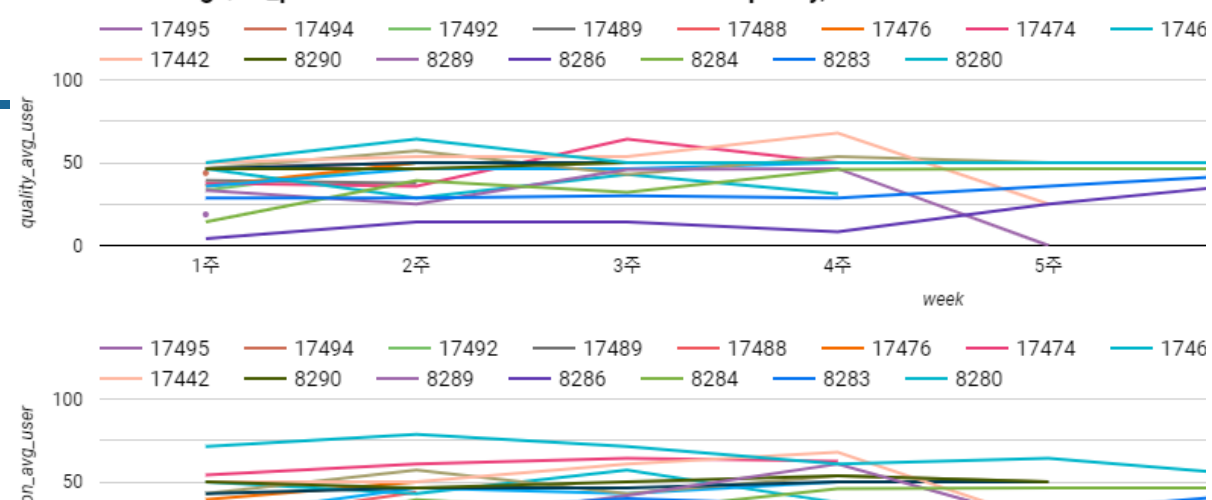
SLEEP QUALITY Fair ENERGY LEVEL Good

Home Sleep Program

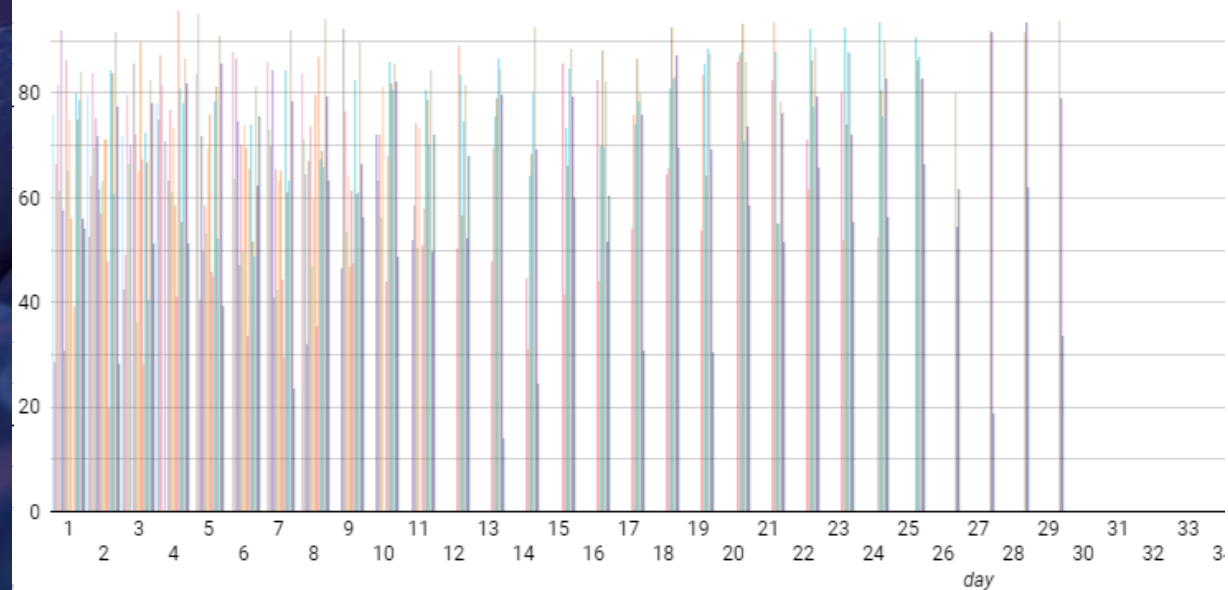
EMR과의 연동



prod weekAvgQnC_perUser - 주차에 따른 32그룹 유저별 quality, condition 의 변화



오늘밤에 잠이 잘 올까?



PILLow Rx - ver 3.0

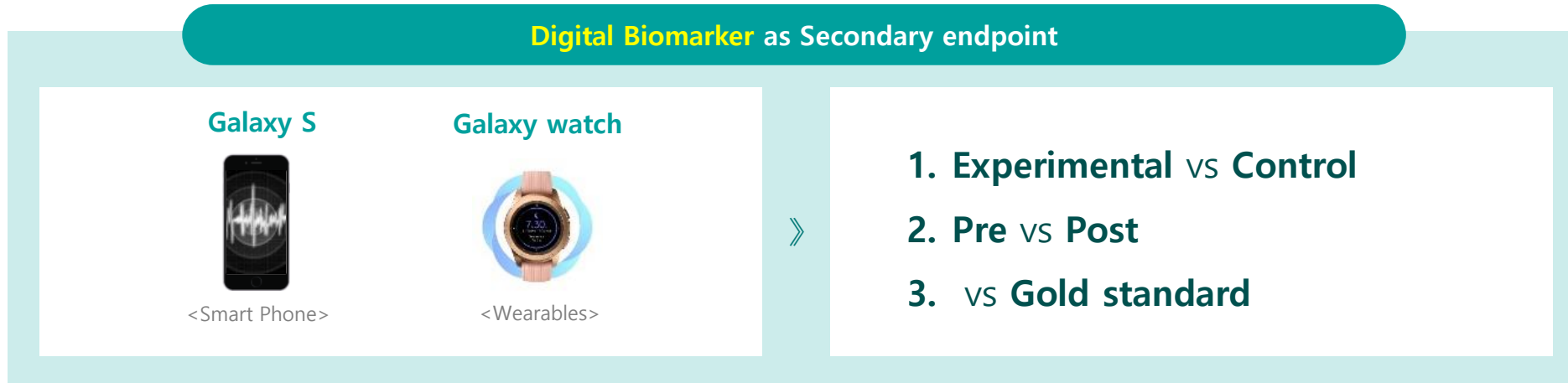
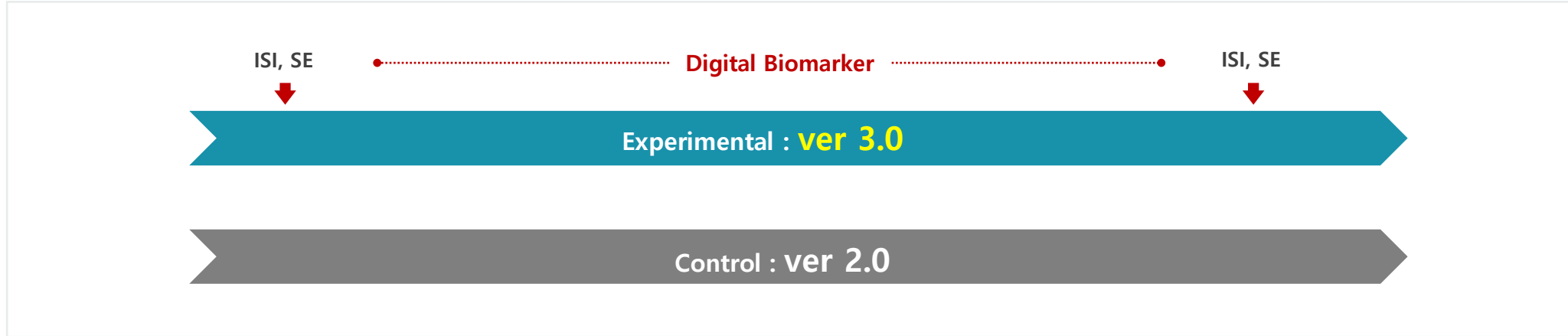
Safety

Efficacy



오늘 생활습관 분석결과
잠이 잘 안 올 것으로 예상되며
처방한 수면제 1알 드시고
1시간 뒤 취침을 권장합니다.

Decentralized Clinical Trial (분산형 임상 = RWE = eQMS)





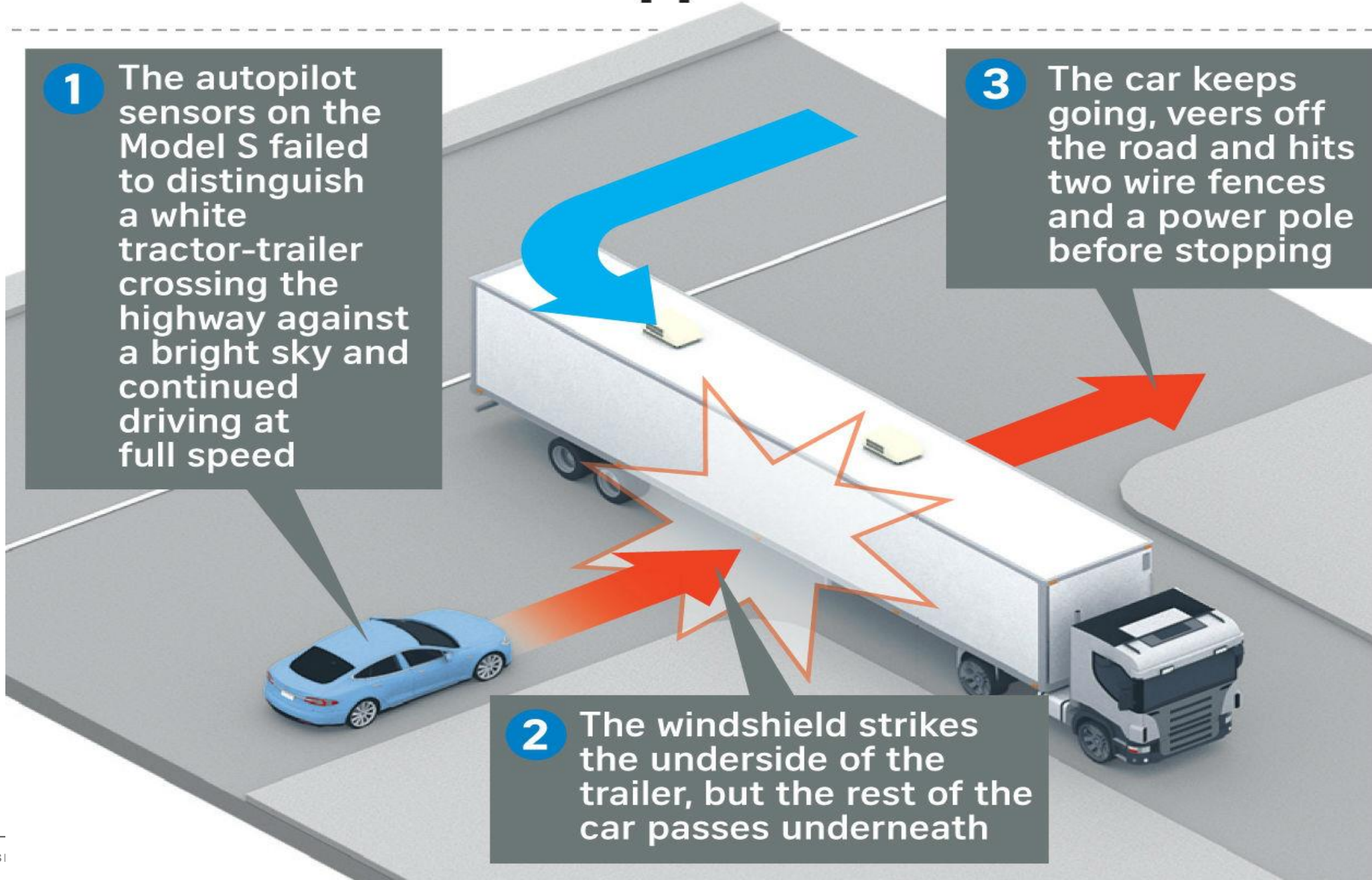
오늘 생활습관 분석결과
수면제 10알 드시고
30분 뒤 취침을 권장합니다.

Tesla crash: How it happened

1 The autopilot sensors on the Model S failed to distinguish a white tractor-trailer crossing the highway against a bright sky and continued driving at full speed

2 The windshield strikes the underside of the trailer, but the rest of the car passes underneath

3 The car keeps going, veers off the road and hits two wire fences and a power pole before stopping



디지털치료기기 허가·심사 가이드라인(민원인 안내서)

2020. 8.



식품의약품안전처
식품의약품안전평가원
의료기기심사부

한번만 봐준다



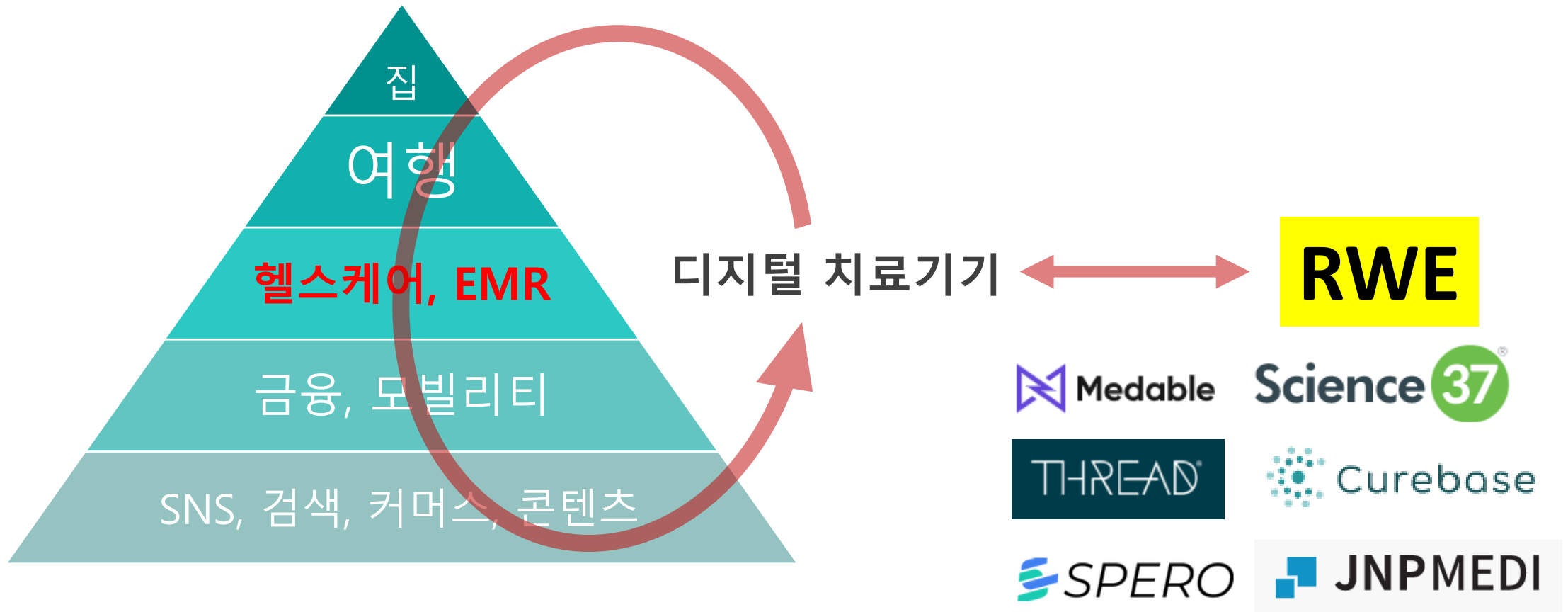
의료기기 소프트웨어 경미한 변경사항 관련 주요 질의응답 사례

2023. 3.



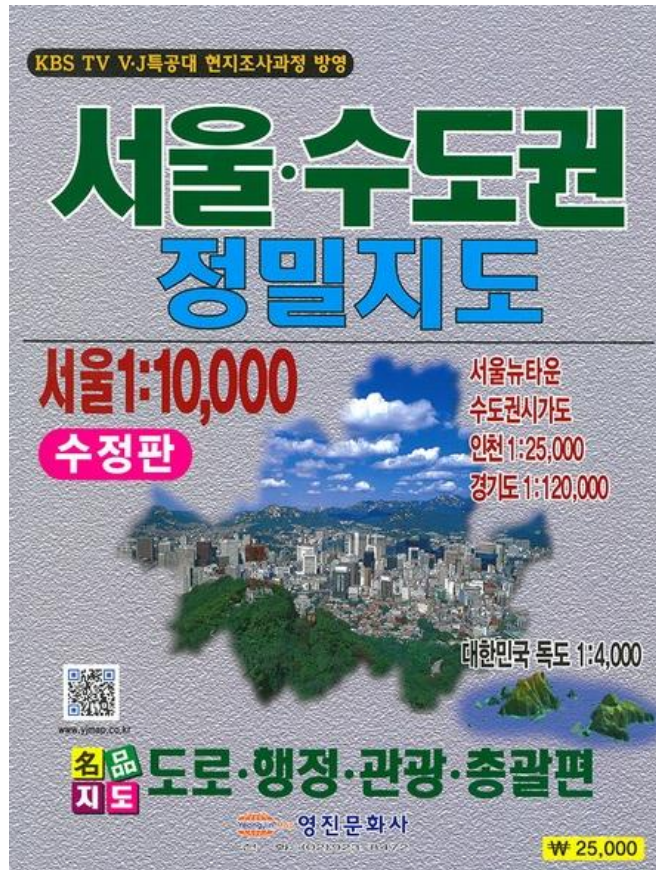
식품의약품안전처
의료기기안전국

My Data, RWD (Real World Data)



기존 치료

운동하시고
건강하게 드세요...



디지털 치료기기

RWD RWE
다양한 데이터 — 더 나은 알고리즘 — 초맞춤형 가이드



SAMSUNG



Now, all you need is
your Galaxy Watch3
to measure blood pressure



APPLE WATCH



초정밀예측 = 보험의 미래

Best compatible with
Galaxy Watch9 Pro

Powered & Guaranteed
by **WELT**

