Digital Therapeutics

디지털 치료제와

산부인과 영역에서의 사용

웰트㈜ 대표이사 강 성 지 MD, MPH

WELT

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- 2020년~ 식품의약안전처 디지털 치료기기 전문가 협의체 위원


[대면진료]


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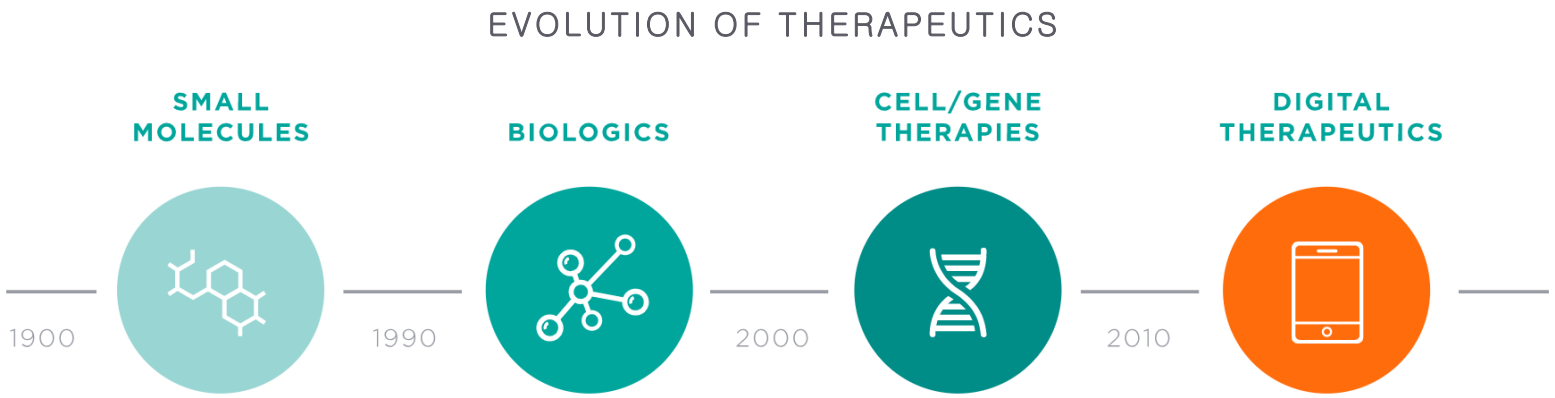
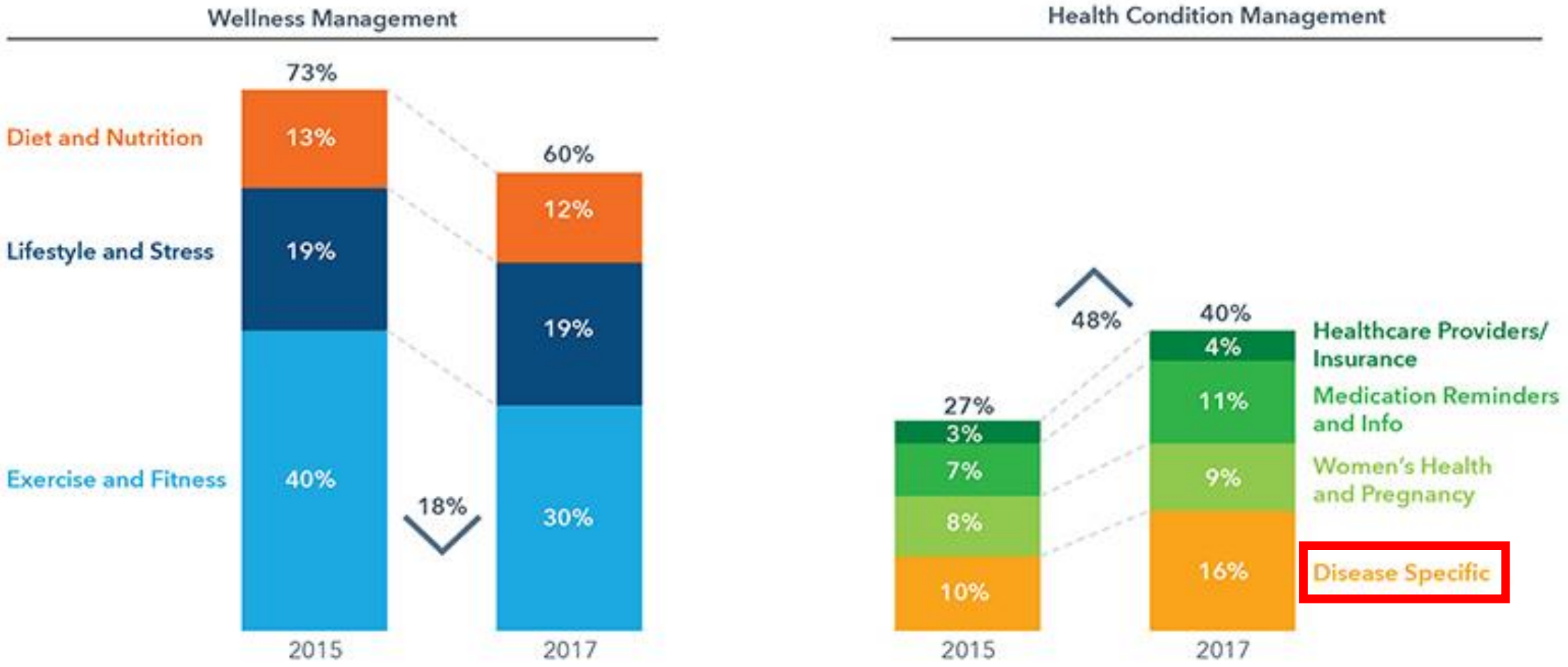
Digital therapeutics : 새로운 형태의 치료법



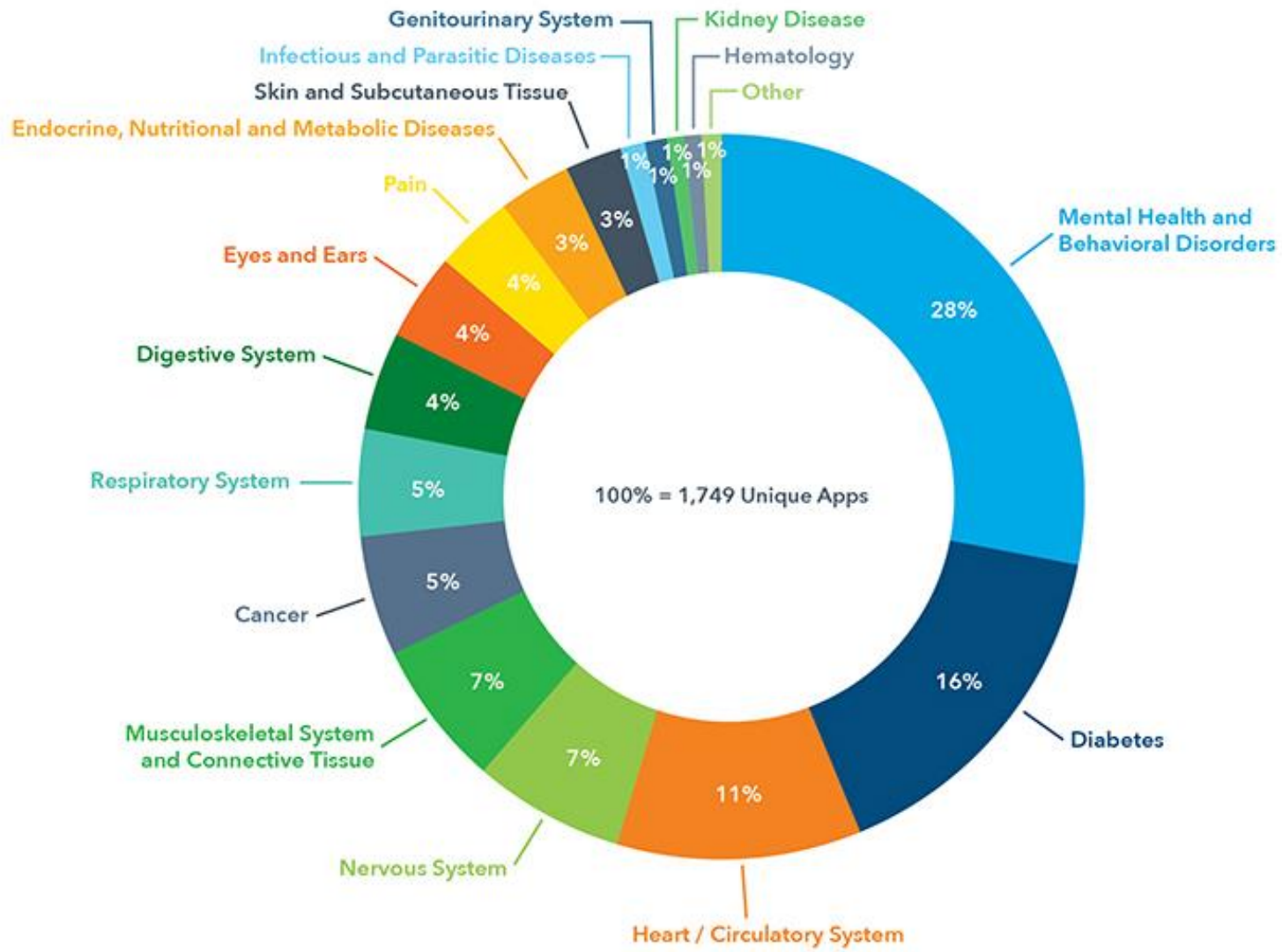
Digital Healthcare solutions by Category



Sources: 42 Matters, Jul 2017; IQVIA AppScript Database, Jul 2017; IQVIA Institute, Jul 2017

Report: The Growing Value of Digital Health. IQVIA Institute for Human Data Science, Nov 2017

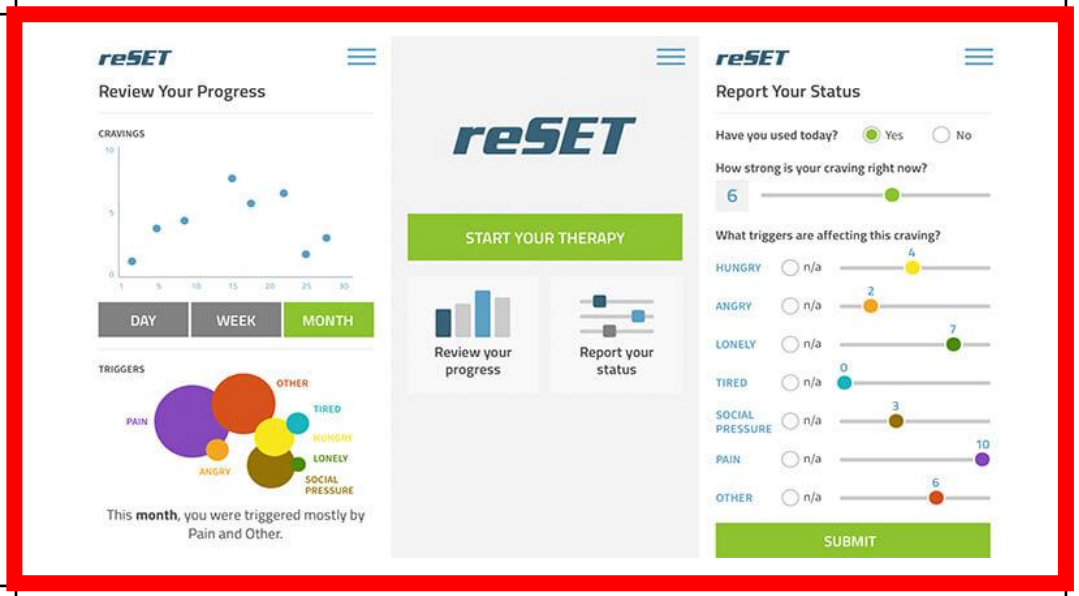
Diseases-Specific Digital Healthcare solutions by Therapy Area



Sources: 42 Matters, Jul 2017; IQVIA AppScript Database, Jul 2017; IQVIA Institute, Jul 2017

Report: The Growing Value of Digital Health. IQVIA Institute for Human Data Science, Nov 2017

하드웨어와 소프트웨어의 분리

	진 단	치 료
소프트웨어 (SaMD)		
하드웨어		

US FDA 의 관점

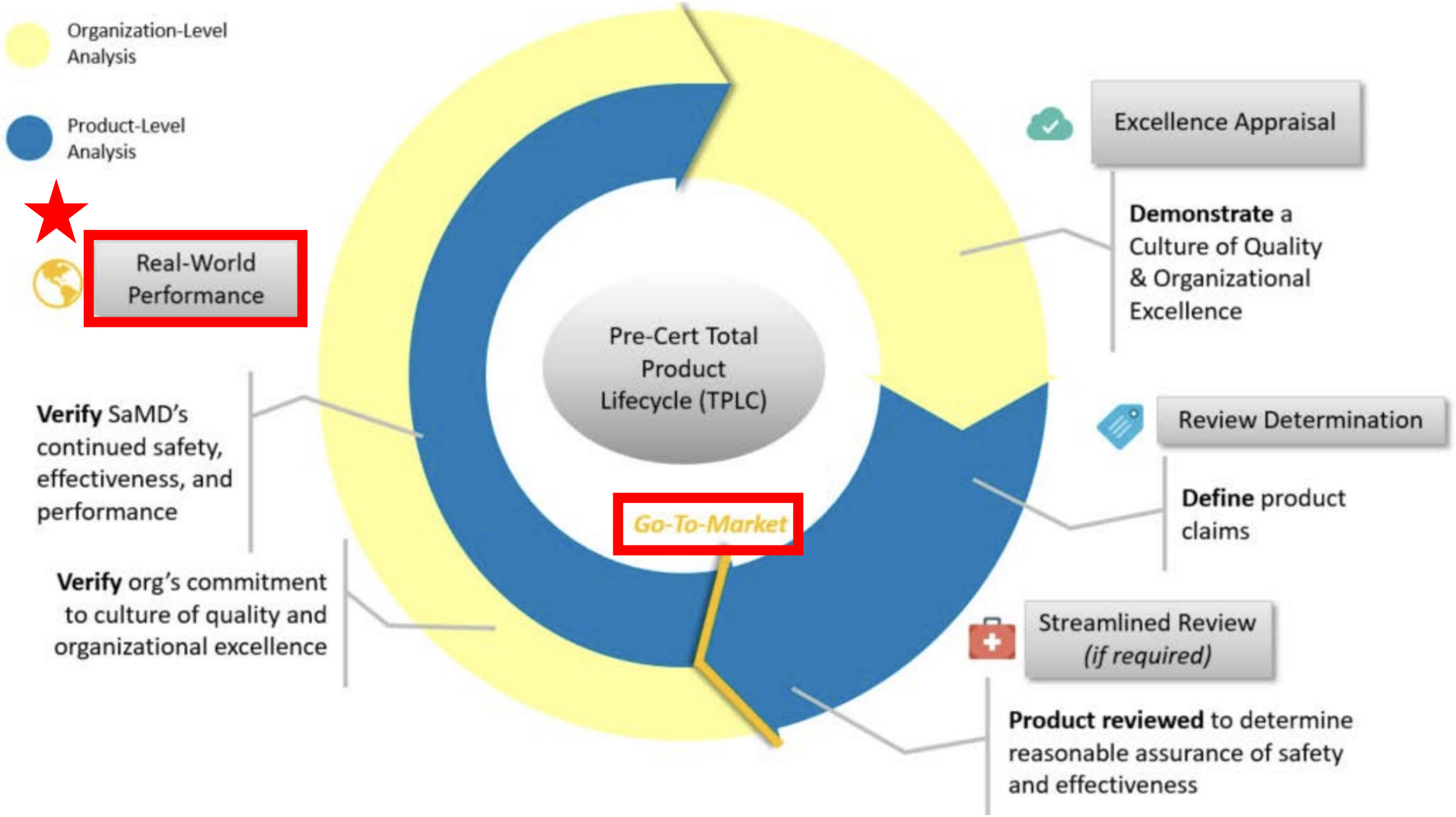
Digital Health Software Precertification Program

is **reimagining** how the FDA regulates digital health devices, specifically **software** as a medical device (SaMD).

FDA, <Software Precertification Program 2019 Mid-Year Update>

FDA is excited to participate in promoting evidenced based safe innovation for a better healthcare system

Bakul Patel, FDA, Director of Digital Health


Organization-Level Analysis
Product-Level Analysis
Real-World Performance
Verify SaMD's continued safety, effectiveness, and performance
Verify org's commitment to culture of quality and organizational excellence
Pre-Cert Total Product Lifecycle (TPLC)
Go-To-Market
Excellence Appraisal
Demonstrate a Culture of Quality & Organizational Excellence
Review Determination
Define product claims
Streamlined Review (if required)
Product reviewed to determine reasonable assurance of safety and effectiveness

☐ 디지털치료기기 대상여부 판단기준 흐름도

KFDA

(1) 독립형 소프트웨어

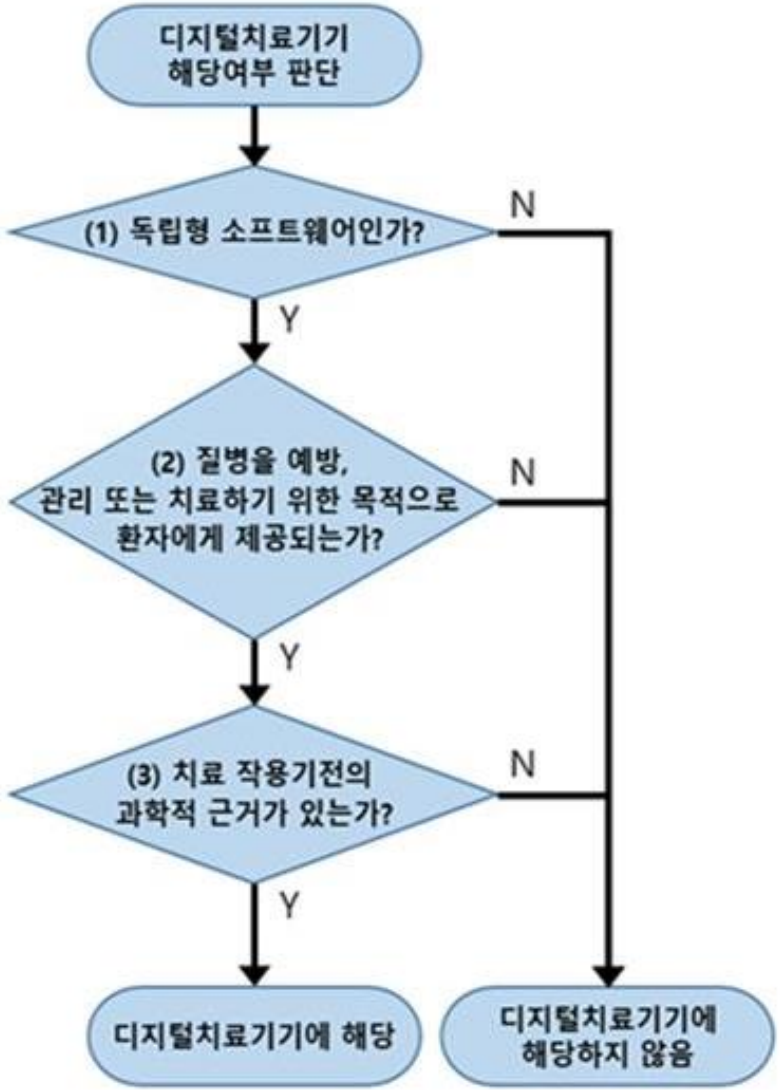
- 디지털치료기기는 단독으로 사용되거나 PC, 모바일제품, HMD 등의 하드웨어 활용 가능

(2) 적용 범위

- 질병 대상 : 국제질병분류(ICD10), 한국표준질병사인분류
  ※ '예방, 관리'는 대상자를 치료적 개입이 필요한 환자로 제한함으로써 치료적 예방, 관리로 해석

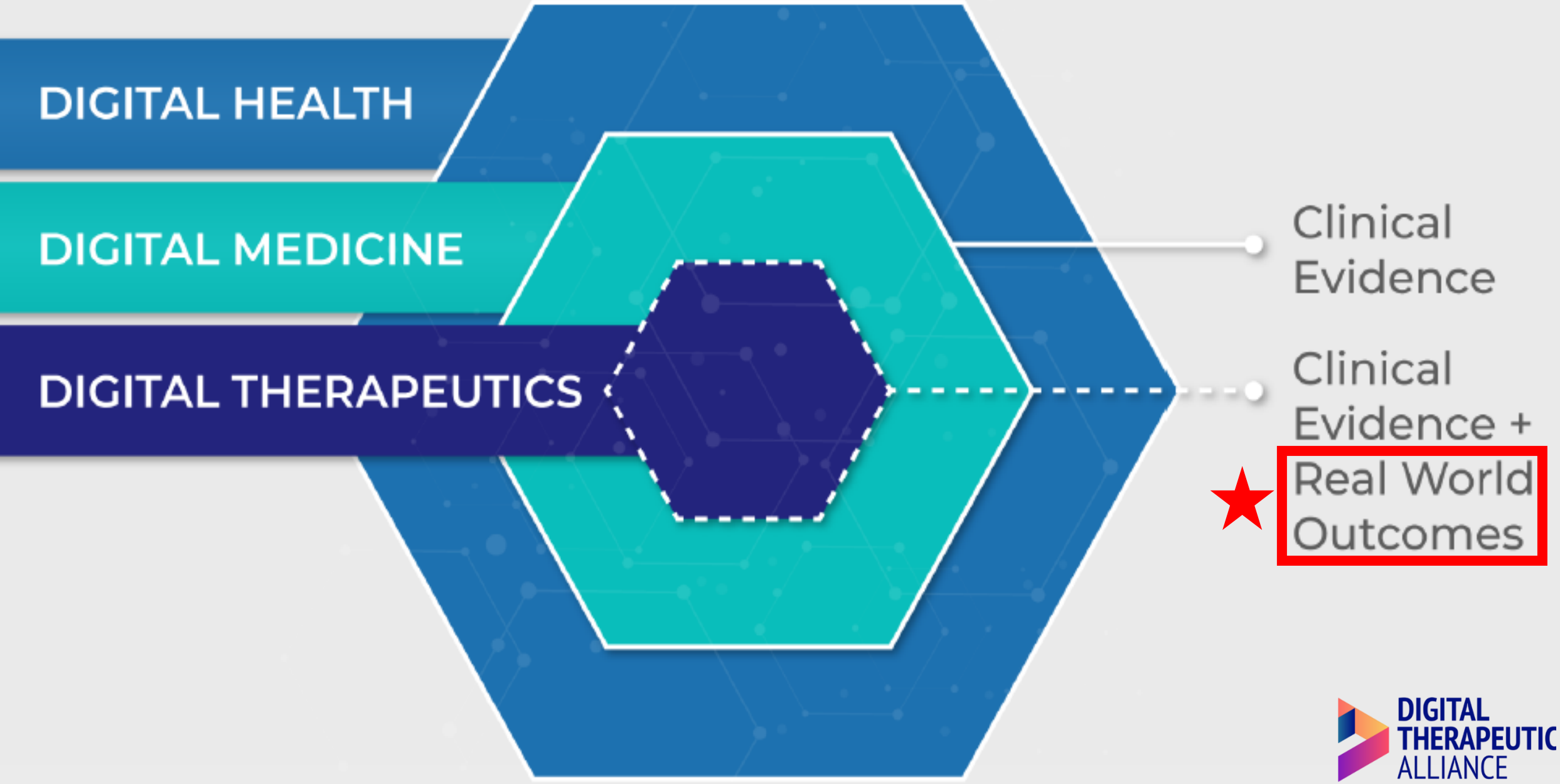
(3) 과학적 근거의 종류

- 치료 관련 작용기전의 과학적 근거는 임상 논문 또는 대한의학회에서 인정한 임상진료지침 (Clinical Practice Guideline, CPG) 등
- 치료의 작용기전은 전문가 검토를 통해 출판된 것 (Peer-reviewed Journal)



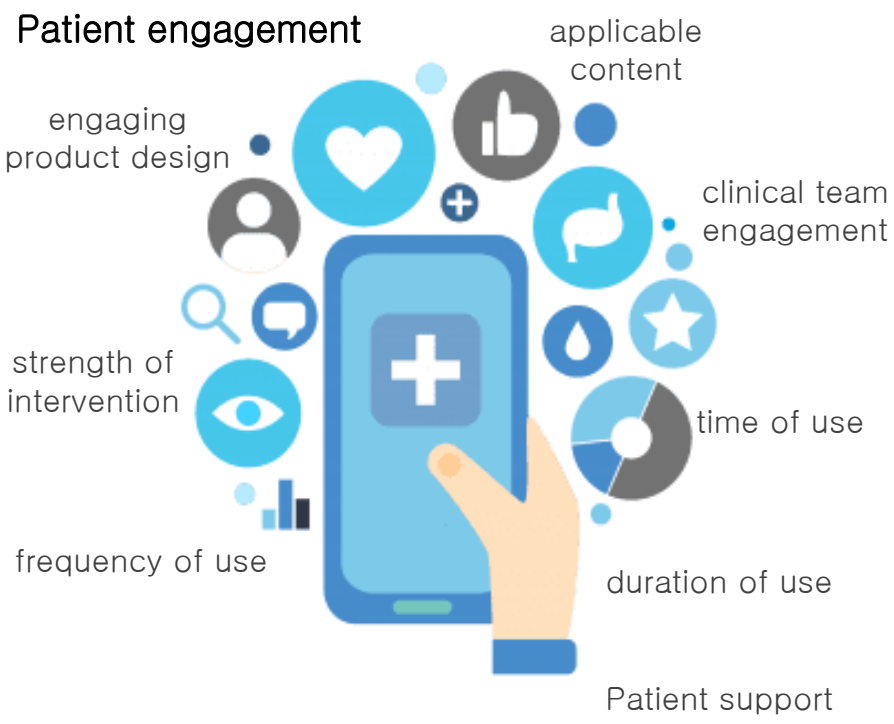
Digital Healthcare

Digital Therapeutics

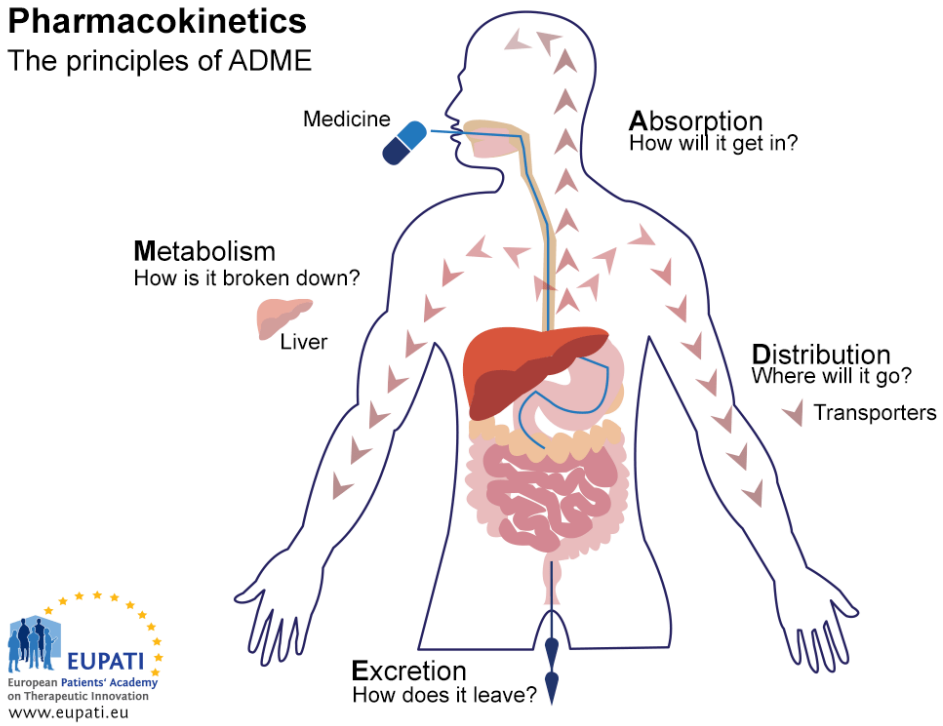

DIGITAL HEALTH
DIGITAL MEDICINE
DIGITAL THERAPEUTICS
Clinical Evidence
Clinical Evidence + Real World Outcomes
DIGITAL THERAPEUTIC ALLIANCE

Digital therapeutics : mechanism of action(MoA)

Digital Therapeutics

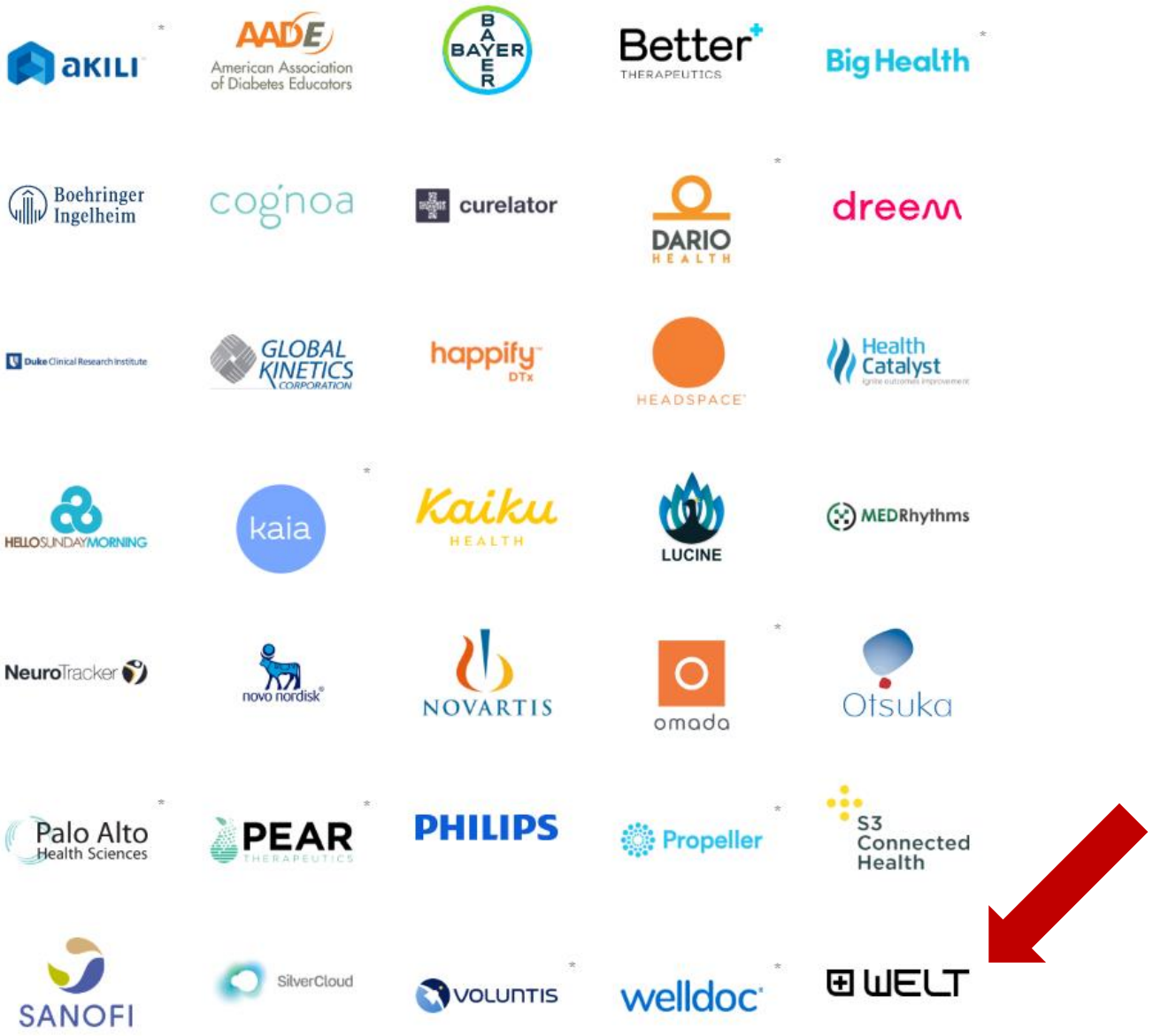


Medications



Member Companies

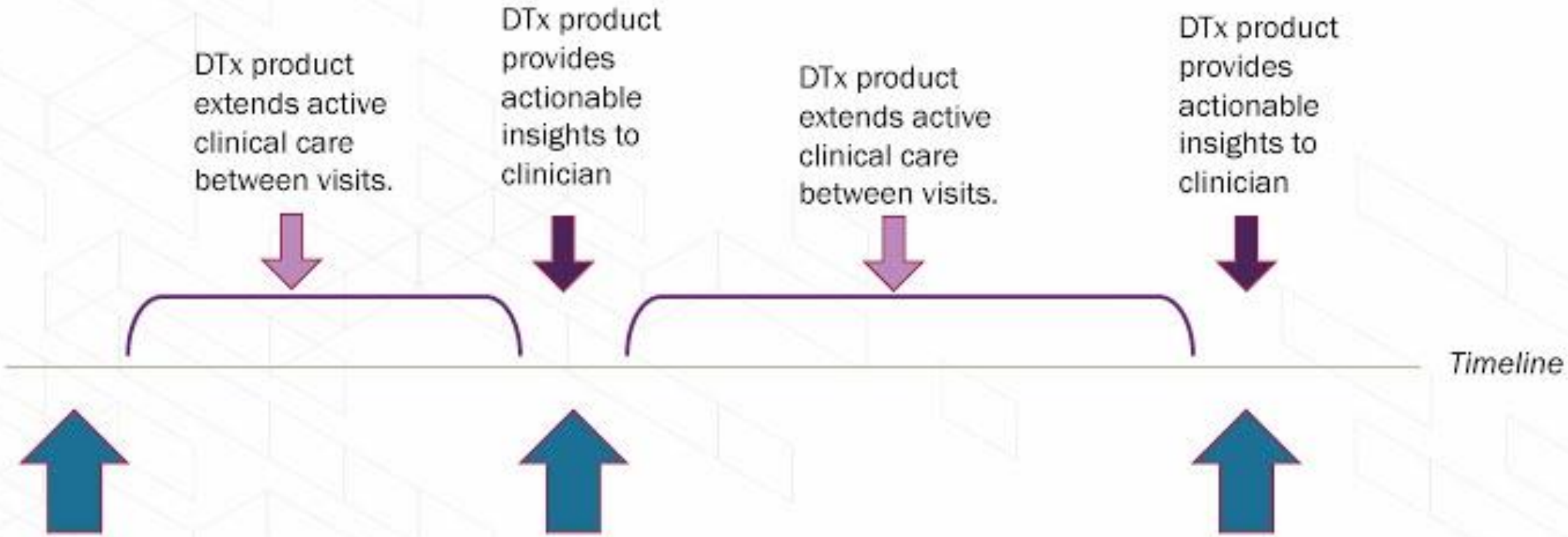
DIGITAL THERAPEUTIC ALLIANCE



What diseases do DTx products target?

- Alcohol use disorder
- Attention-deficit/hyperactivity disorder (ADHD)
- Anxiety
- Asthma
- Autism spectrum disorder
- Cancer
- Cardiovascular disease
- Central nervous system (CNS) disorders
- Chronic obstructive pulmonary disease (COPD)
- Coagulation disorders
- Cognition
- Depression
- Diabetes, type 1
- Diabetes, type 2
- Eating disorders
- Epilepsy
- Gastrointestinal disorders
- Hemophilia
- Hypertension
- ICU delirium
- Immunological disorders
- Inflammation disorders
- Insomnia
- Irritable bowel syndrome (IBS)
- Lupus
- Mental health disorders
- Metabolic syndrome
- Migraine
- Movement disorders
- Multiple sclerosis (MS)
- Obesity
- Opioid use disorder (OUD)
- Pain, acute
- Pain, chronic
- Panic attacks
- Parkinson's disease (PD)
- Post-traumatic stress disorder (PTSD)
- Respiratory diseases
- Rare diseases
- Schizophrenia (positive symptoms)
- Skin disorders
- Sleep disorders
- Stress-related chronic diseases
- Stroke
- Substance use disorder (SUD)
- Traumatic brain injury (TBI)

How do DTx products help clinicians in outpatient settings?



DTx US Payment Pathways Document*

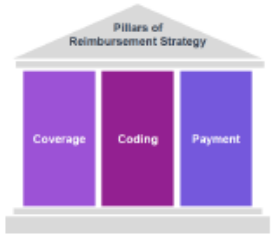
*For full document, please access via DTA's Dropbox

Digital Therapeutics Alliance
Resources for U.S. Based DTx Reimbursement Pathways
Draft by: Jen Lavanture and Owen McCarthy

Reimbursement for healthcare products, including digital therapeutics, is a vital component to providing patient access to new technologies. Given the diverse nature of digital therapeutics and the broad range of therapeutic applications, a "one-size-fits-all" approach to reimbursement strategy for digital therapeutics is unlikely to reflect the realities of current reimbursement pathways in the United States and may overlook opportunities to ensure optimal access and value.

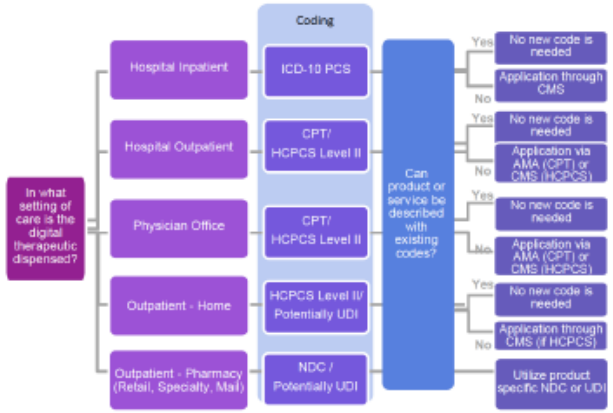
Digital therapeutics (DTx) deliver evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. Successful DTx reimbursement strategies will consider the requirements across the full market access landscape, including: 1) value demonstration (clinical and economic data); 2) stakeholder engagement; 3) reimbursement pathway and pricing (coding, coverage, and payment); and 4) policy development and implementation. While all of the aforementioned categories are critical components in gaining and maintaining market access, this document focuses on clarifying the reimbursement pathways available for digital therapeutics and is intended to serve as a guide in assessing optimal pathways.

Pillars of Reimbursement Strategy
Reimbursement strategy for digital therapeutics can be thought of in terms of three separate components: 1) Coverage, 2) Coding, and 3) Payment. While these are often used interchangeably, approaching them as discrete components of reimbursement will support optimization of each portion as part of the broader reimbursement pathway.



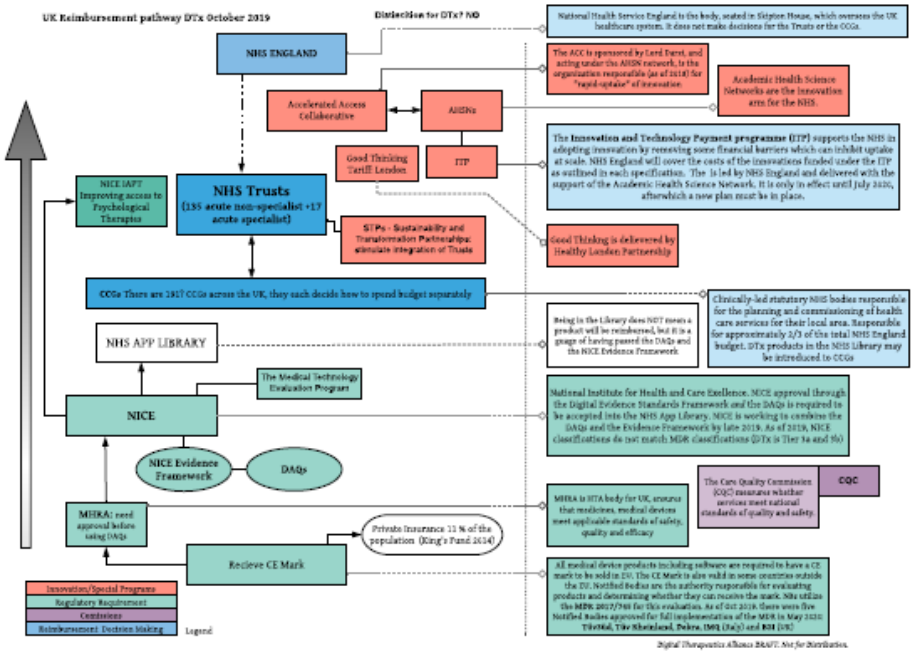
Identifying a pathway to reimbursement in the U.S. is complicated by the fragmented healthcare delivery and payment model, which includes a mix of public and private payers, division of coverage and payment between medical and pharmacy benefits, and multiple coding and payment methodologies.

Code Identification Decision Tree



United Kingdom Coverage Pathway*

*For full document, please access via DTA's Dropbox



Germany Coverage Pathway*

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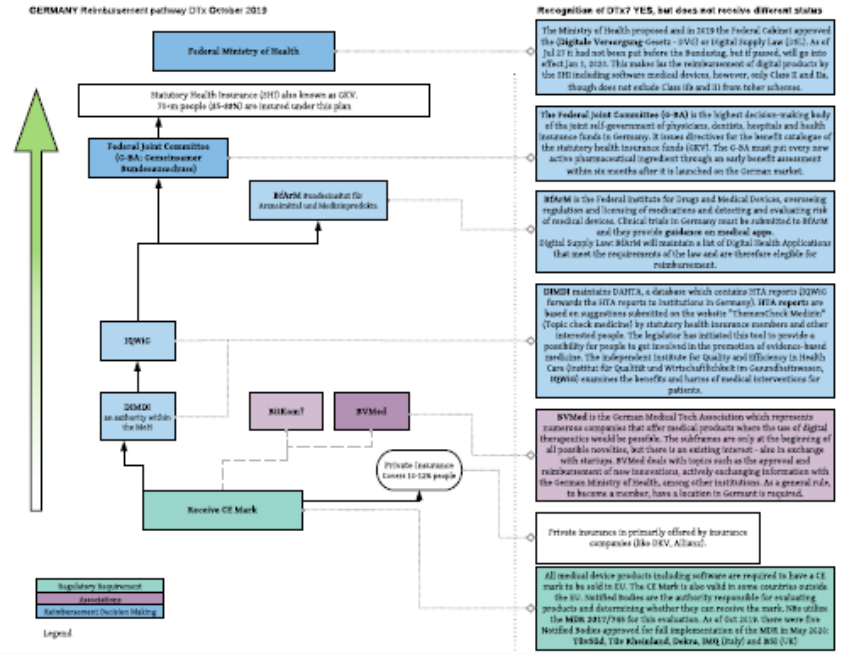

France Coverage Pathway*

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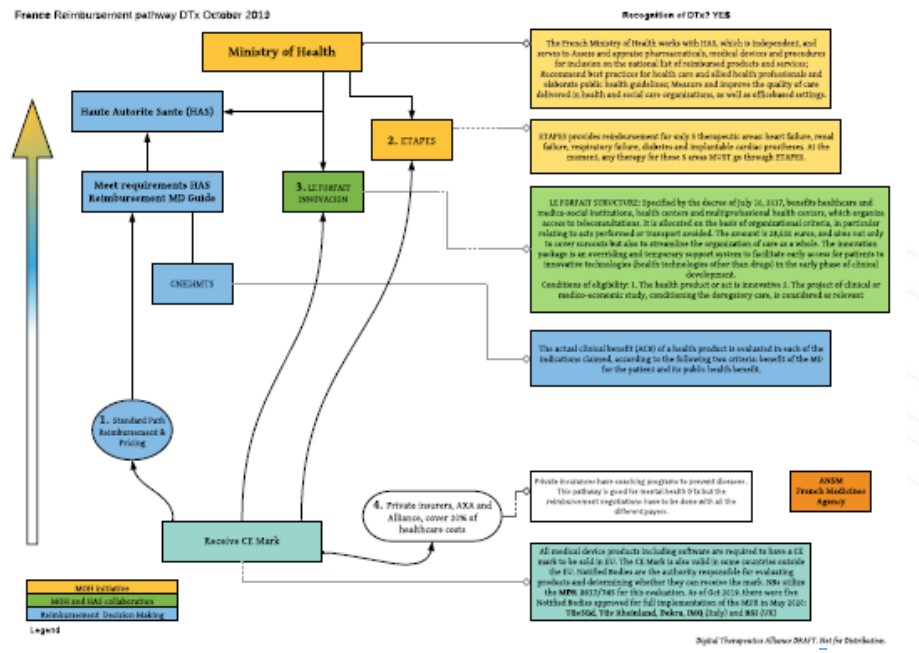
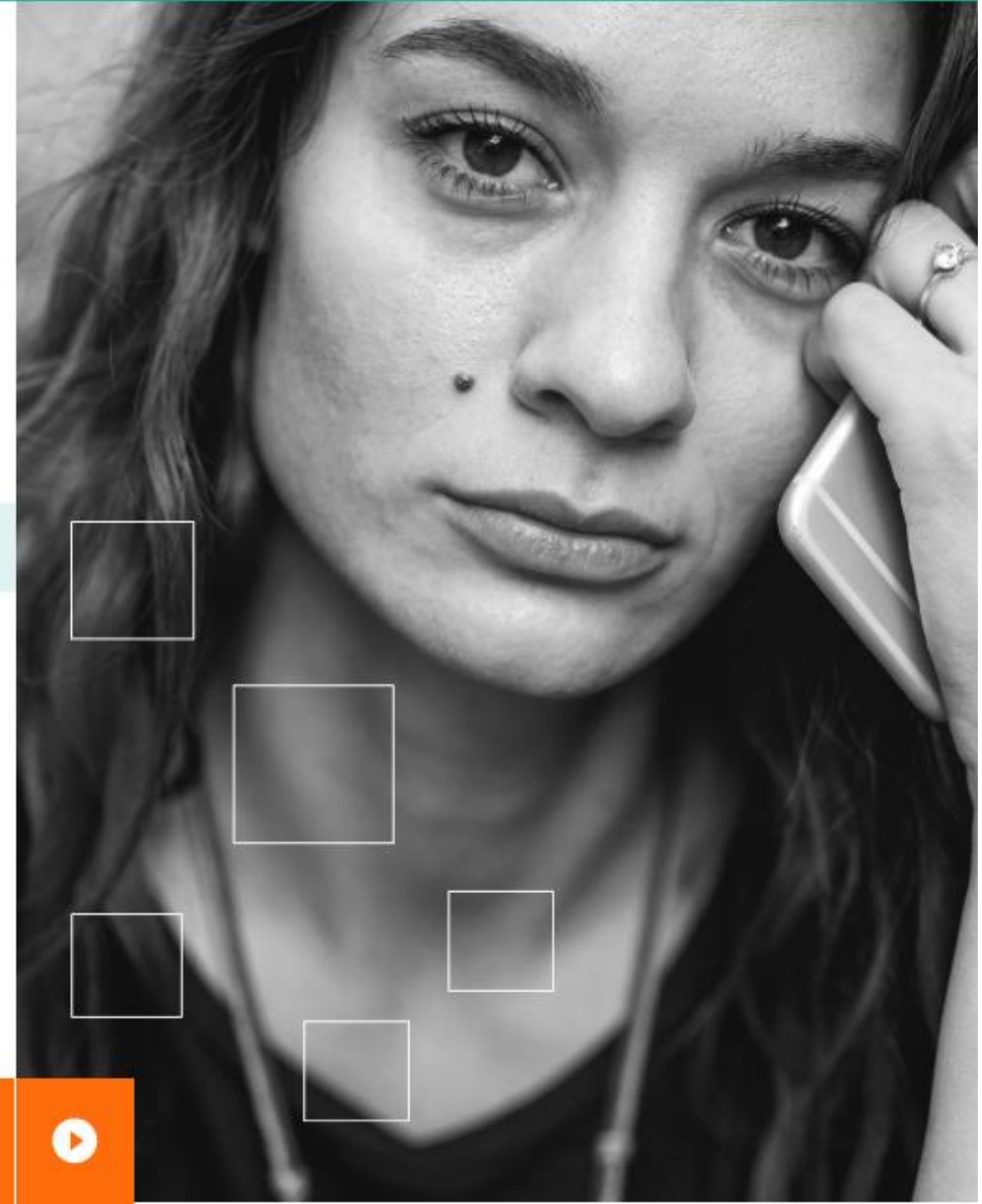


PEAR THERAPEUTICS

Redefining Medicine

PRESCRIPTION DIGITAL THERAPEUTICS FOR THE TREATMENT OF SERIOUS DISEASE



WATCH THE VIDEO

Internet-Delivered Treatment for Substance Abuse: A Multisite Randomized Controlled Trial

Aimee N.C. Campbell, Ph.D.
Edward V. Nunes, M.D.
Abigail G. Matthews, Ph.D.
Maxine Stitzer, Ph.D.
Gloria M. Miele, Ph.D.
Daniel Polsky, Ph.D.
Eva Turrigiano, M.S.
Scott Walters, Ph.D.
Erin A. McClure, Ph.D.
Tiffany L. Kyle, Ph.D.
Aimee Wahle, M.S.
Paul Van Veldhuisen, Ph.D.
Bruce Goldman, L.C.S.W.
Dean Babcock, L.C.S.W.
Patricia Quinn Stabile, L.C.S.W.
Theresa Winhusen, Ph.D.
Udi E. Ghitza, Ph.D.

Objective: Computer-delivered interventions have the potential to improve access to quality addiction treatment care. The objective of this study was to evaluate the effectiveness of the Therapeutic Education System (TES), an Internet-delivered behavioral intervention that includes motivational incentives, as a clinician-extender in the treatment of substance use disorders.

Method: Adult men and women (N=507) entering 10 outpatient addiction treatment programs were randomly assigned to receive 12 weeks of either treatment as usual (N=252) or treatment as usual plus TES, with the intervention substituting for about 2 hours of standard care per week (N=255). TES consists of 62 computerized interactive modules covering skills for achieving and maintaining abstinence, plus prize-based motivational incentives contingent on abstinence and treatment adherence. Treatment as usual consisted of individual and group counseling at the participating programs. The primary outcome measures were abstinence from drugs and heavy drinking (measured by twice-weekly urine drug screens and self-report) and time to dropout from treatment.

Results: Compared with patients in the treatment-as-usual group, those in the TES group had a lower dropout rate (hazard ratio=0.72, 95% CI=0.57, 0.92) and a greater abstinence rate (odds ratio=1.62, 95% CI=1.12, 2.35). This effect was more pronounced among patients who had a positive urine drug or breath alcohol screen at study entry (N=228) (odds ratio=2.18, 95% CI=1.30, 3.68).

Conclusions: Internet-delivered interventions such as TES have the potential to expand access and improve addiction treatment outcomes. Additional research is needed to assess effectiveness in nonspecialty clinical settings and to differentiate the effects of the community reinforcement approach and contingency management components of TES.

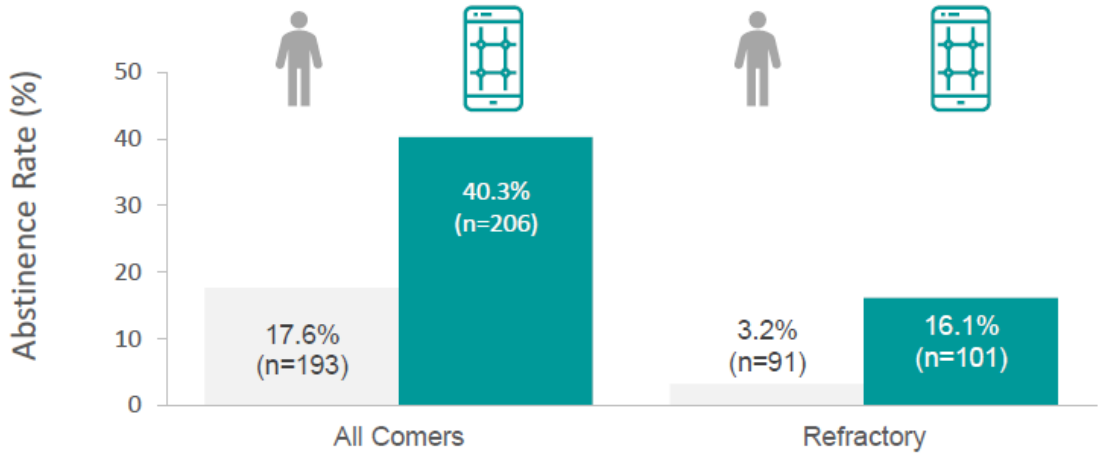
reSET clinical trial shows superior outcomes versus treatment as usual

Pivotal Registration Study

PIVOTAL TRIAL OVERVIEW

- 399 patients with Substance Use Disorder (SUD) (alcohol, cannabis, cocaine, stimulants) received either;
  - Treatment as Usual (TAU); intensive face-to-face therapy), or
  - Reduced TAU + reSET for 12 weeks[1]
- Patients provide urine samples twice per week to objectively monitor abstinence
- Co-primary endpoints
  - Abstinence in weeks 9-12
  - Retention in treatment

STUDY RESULTS[1]



			P-Value
Abstinence (All)	17.6%	40.3%	0.0004
Abstinence (Refractory)	3.2%	16.1%	0.0013
Retention (All)	63.2%	76.2%	0.0042

[1]Campbell et al., American Journal of Psychiatry. 2014. 171(6):683-690.
[2]Pear Internal data and Pear regulatory submission: DEN 160018 FDA Decision Summary.

reSET and reSET-O are designed to redefine treatment of Substance Use Disorder (SUD) and Opioid Use Disorder (OUD)

- First-ever PDT to achieve FDA medical claims to treat disease[1]
- Monotherapy to treat patients suffering from SUD under the supervision of a clinician
- Two RCTs in >1,000 SUD patients (alcohol, cannabis, cocaine, stimulants)[1-3]

- First-ever PDT to receive Breakthrough Designation[4]
- Combination with buprenorphine to treat patients with OUD under the supervision of a clinician[4,5]
- 3 RCTs in >450 OUD patients: 2 with reSET-O + buprenorphine and 1 with reSET-O + methadone[4-7]

[1]DEN 160018 FDA Decision Summary.
[2]Campbell et al., American Journal of Psychiatry. 2014. 171(6):683-690.
[3]Chaple et al. 2016. The Prison Journal. 96(3):485-508.
[4]Internal data, FDA Regulatory filing, K173681, and Maricich Y et al. Safety and Efficacy of reSET in Patients w/ OUD. AAAP Annual Conference, 2018

[5]Christensen et al. J Consult Clin Psychol. 2014;82(6):964-972.
[6]Bickel et al. Exp Clin Psychopharmacol. 2008;16(2):132-143.
[7]Marsch et al. Subst Abuse Treat. 2014;46(1):43-51.

Complete 4 lessons

Weekly · 4 days left

NEXT LESSON

Conducting a Functional Analysis

START LESSON

TRACK YOUR RECOVERY

Record recent cravings, triggers, or substance use.

CHECK IN

Home | Lessons | Insights | Rewards | Settings

2:41 3G

Lessons

CORE LESSONS

1 of 31 completed

- What is a Functional Analysis?
- Conducting a Functional Analysis
- Self-Management Planning
- Introduction to Problem Solving
- Effective Problem Solving
- Drug Refusal Skills Training
- Seemingly Irrelevant Decisions
- Coping with Thoughts About Using
- Awareness of Negative Thinking

Home | Lessons | Insights | Rewards | Settings

2:42 3G

Insights | Cravings Check In

Have you used today?

Required

Yes | No

How strong is your craving right now? 2

What triggers are affecting this craving?

Hunger 3

Anger 2

Loneliness 5

SUBMIT

10:54

Congratulations!

Tap the screen to spin the wheel for a chance to win a reward!

THE LANCET
Psychiatry

ARTICLES | VOLUME 3, ISSUE 4, P333-341, APRIL 01, 2016

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Effectiveness of an online insomnia program (SHUTi) for prevention of depressive episodes (the GoodNight Study): a randomised controlled trial

Prof Helen Christensen, PhD † • Philip J Batterham, PhD † • John A Gosling, BSc † • Prof Lee M Ritterband, PhD • Prof Kathleen M Griffiths, PhD • Frances P Thorndike, PhD • et al. Show all authors • Show footnotes

Published: January 27, 2016 • DOI: https://doi.org/10.1016/S2215-0366(15)00536-2 • Check for updates

Summary

Background

In view of the high co-occurrence of depression and insomnia, a novel way to reduce the risk of escalating depression might be to offer an insomnia intervention. We aimed to assess whether an online self-help insomnia program could reduce depression symptoms.

Methods

We did this randomised controlled trial at the Australian National University in Canberra, Australia. Internet users (aged 18–64 years) with insomnia and depression symptoms, but who did not meet criteria for major depressive disorder, were randomly assigned (1:1), via computer-generated randomisation, to receive SHUTi, a 6 week, modular, online insomnia program based on cognitive behavioural therapy for insomnia, or HealthWatch, an interactive, attention-matched, internet-based placebo control program. Randomisation was stratified by age and sex. Telephone-based interviewers, statisticians, and chief investigators were masked to group allocation. The primary outcome was depression symptoms at 6 months, as measured with the Patient Health Questionnaire (PHQ-9). The primary analysis was by intention to treat. This trial is registered with the Australian New Zealand Clinical Trials

JAMA Psychiatry | Original Investigation

Effect of a Web-Based Cognitive Behavior Therapy for Insomnia Intervention With 1-Year Follow-up
A Randomized Clinical Trial

Lee M. Ritterband, PhD; Frances P. Thorndike, PhD; Karen S. Ingersoll, PhD; Holly R. Lord, PhD; Linda Gonder-Frederick, PhD; Christina Frederick, BS; Mark S. Quigg, MD, MSc; Wendy F. Cohn, PhD; Charles M. Morin, PhD

Editorial page 15
Supplemental content

IMPORTANCE Although cognitive behavior therapy for insomnia (CBT-I) has been established as the first-line recommendation for the millions of adults with chronic insomnia, there is a paucity of trained clinicians to deliver this much needed treatment. Internet-delivered CBT-I has shown promise as a method to overcome this obstacle; however, the long-term effectiveness has not been proven in a representative sample with chronic insomnia.

OBJECTIVE To evaluate a web-based, automated CBT-I intervention to improve insomnia in the short term (9 weeks) and long term (1 year).

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial comparing the internet CBT-I with internet patient education at baseline, 9 weeks, 6 months, and 1 year. Altogether, 303 adults with chronic insomnia self-referred to participate, of whom 151 (49.8%) reported at least 1 medical or psychiatric comorbidity.

INTERVENTIONS The internet CBT-I (Sleep Healthy Using the Internet [SHUTi]) was a 6-week fully automated, interactive, and tailored web-based program that incorporated the primary tenets of face-to-face CBT-I. The online patient education program provided nontailored and fixed online information about insomnia.

MAIN OUTCOMES AND MEASURES The primary sleep outcomes were self-reported online ratings of insomnia severity (Insomnia Severity Index) and online sleep diary–derived values for sleep-onset latency and wake after sleep onset, collected prospectively for 10 days at each assessment period. The secondary sleep outcomes included sleep efficiency, number of awakenings, sleep quality, and total sleep time.

RESULTS Among 303 participants, the mean (SD) age was 43.28 (11.59) years, and 71.9% (218 of 303) were female. Of these, 151 were randomized to the SHUTi group and 152 to the online patient education group. Results of the 3 primary sleep outcomes showed that the overall group × time interaction was significant for all variables, favoring the SHUTi group (Insomnia Severity Index [$F_{3,1063}$ = 20.65, P < .001], sleep-onset latency [$F_{3,1042}$ = 6.01, P < .001], and wake after sleep onset [$F_{3,1042}$ = 12.68, P < .001]). Within-group effect sizes demonstrated improvements from baseline to postassessment for the SHUTi participants (range, Cohen d = 0.79 [95% CI, 0.55-1.04] to d = 1.90 [95% CI, 1.62-2.18]). Treatment effects were maintained at the 1-year follow-up (SHUTi Insomnia Severity Index d = 2.32 [95% CI, 2.01-2.63], sleep-onset latency d = 1.41 [95% CI, 1.15-1.68], and wake after sleep onset d = 0.95 [95% CI, 0.70-1.21]), with 56.6% (69 of 122) achieving remission status and 69.7% (85 of 122) deemed treatment responders at 1 year based on Insomnia Severity Index data. All secondary sleep outcomes, except total sleep time, also showed significant overall group × time interactions, favoring the SHUTi group.

CONCLUSIONS AND RELEVANCE Given its efficacy and availability, internet-delivered CBT-I may have a key role in the dissemination of effective behavioral treatments for insomnia.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01438697

JAMA Psychiatry. 2017;74(1):68-75. doi:10.1001/jamapsychiatry.2016.3249
Published online November 30, 2016.

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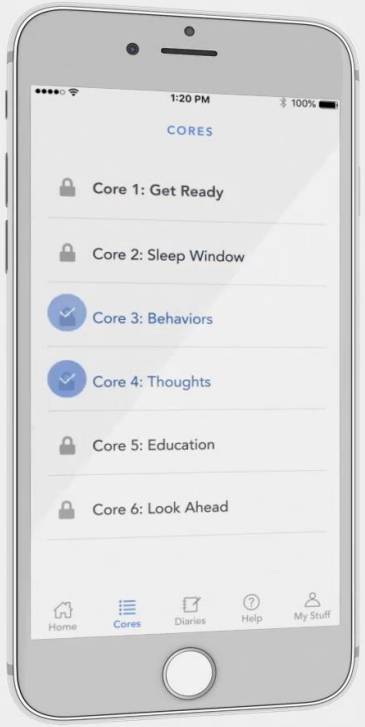
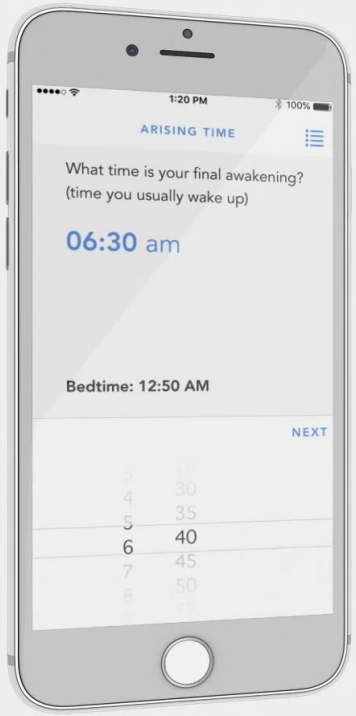
Somryst

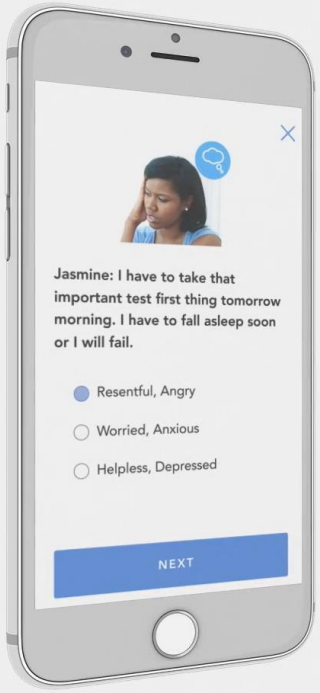
6 core units



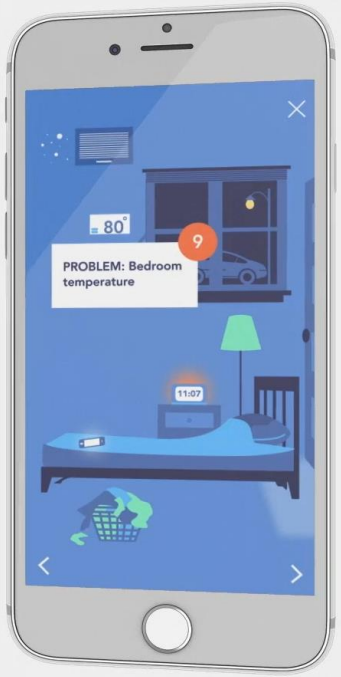
Tailor sleep window behaviors & cognition



rate sleep experiences & progress

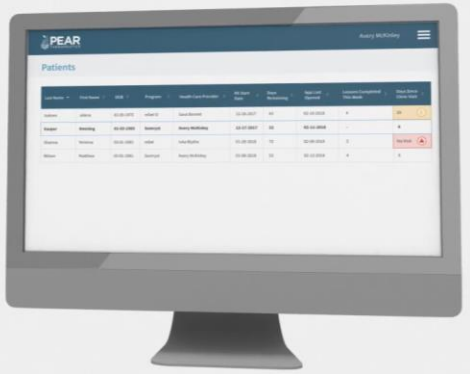


identify & manage sleep stimuli



maximize sleep time

9 week prescription real-time view



Pear has a robust pipeline of PDTs and product candidates

Company	Product	Indication	Description	Cleared/ approved date	Rx	Price
Therapeutics						
Pear Therapeutics Inc. / **Novartis AG** (NYSE:NVS; SIX:NOVN)	reSET	Substance use disorder	90-day cognitive behavior therapy program as adjunct to contingency management in outpatient treatment	2017	yes	$1,300
	reSET-O	Opioid use disorder	84-day cognitive behavior therapy program as adjunct to transmucosal buprenorphine and contingency management in outpatient treatment	2018	yes	$1,500

S ets Research
Future, Zion Market Research. Karolinska transaction is with individual researchers who are employed by the Karolinska Institute.

Sanofi, Happify Health to Develop Digital Therapeutics for MS Patients

Posted on: September 19, 2019 in News | Biotech News | Medical Device News | Medical Device Videos

By: Candice Tang, MSc.

Following development of the MS-specific digital therapeutic, Happify and Sanofi will need to submit safety and efficacy data in hopes FDA clearance.

Digital therapeutics took off in the healthcare industry last year, notably when Pear Therapeutics and Novartis signed an agreement to develop these technologies together. Now, a new duo is joining the digital therapeutics bandwagon: biopharmaceutical company Sanofi and digital health tech innovator Happify Health announced a partnership to develop

VOLUNTIS

TheraXium ONCOLOGY

Oleena™

Partner: AstraZeneca

Target: Oncology
Product: Companion software (symptoms management and patient monitoring)

Class II SaMD

Livongo™

Target: Diabetes
Product: BG measurement, personalized feedback to drive lifestyle changes
Cellular enabled glucometer integrated CDE support

Founded: 2014
Headquarters: Mountain View, CA
Status: Public (NASDAQ)

Total Funding: $600M (IPO)
Revenue: $68.9M
Employees: 635

679 clients
164,000 members

Livongo Health Inc. (NASDAQ:LVGO)	Livongo for diabetes	Diabetes	Blood glucose meter (biomarker) connected to diabetes tracking app (tool)	2014	no	NA
Welldoc Inc.	BlueStar	Type II diabetes	App for diabetes management, uses manually input glucose readings	2017	no	$58

WELT

BUSINESS

Teladoc Health to Acquire Livongo Health in $18.5 Billion Deal

Provider of virtual-care services looks to enhance ability to monitor patients' health

TECH

Teladoc and Livongo merge into $37 billion remote-health company as coronavirus keeps patients home

PUBLISHED WED, AUG 5 2020•2:19 PM EDT | UPDATED WED, AUG 5 2020•6:59 PM EDT

"With COVID-19 we started to see the digital health and digital therapeutics industry moving forward," Raphael told *MD+DI*. "But it was a struggle for many years because things were moving along very slow."

뉴스홈 | 최신기사

국립정신건강센터, 웰트와 '디지털 치료제' 국내 도입 MOU 체결

송고시간 | 2020-08-04 09:47

의사가 처방하는 정신질환 '디지털치료제' 도입 추진한다

국립정신건강센터, 웰트와 업무협약 체결...美 페어 테라퓨틱스 중독치료용 앱 도입 추진
'혁신의료기기 지원법' 시행으로 법적 근거 마련돼...라이프시맨틱스 등 디지털치료제 보유

김상기 기자 승인 2020.08.04 16:03 댓글 0

복지부-웰트 디지털치료제 도입 업무협약

파이낸셜뉴스 입력 2020.08.04 10:41 수정 2020.08.04 10:53

국립정신건강센터
National Center for Mental Health

WELT

① 알코올 중독

Measurement

디지털 바이오마커 기반 금단 및 스트레스 반응성 모니터링*

PHASE I

<Smart Phone>

- Withdrawal Symptoms
- Non-Contact Monitoring

PHASE II

<3rd Party Wearables>

- WELT DSP Algorithm
- Data Integration

Biomarker Cravings & Trigger / Withdrawal Symptoms / Tremor, Palpitation with 3rd Party Wearable / Sleep Onset Latency / Cycle & Pattern

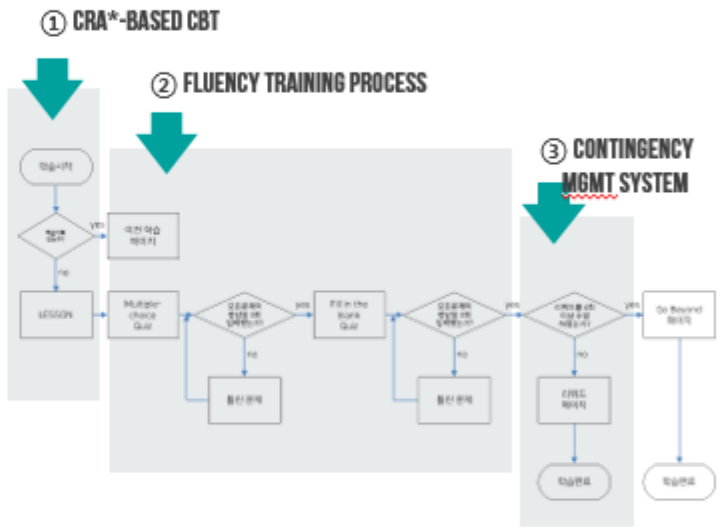
Personalized Feedback based on RWD

*Critical for Treatment Outcome

WELT-A

Treatment

FDA approved Digital CBT 기반 치료 모델



Compared to TAU, study results show**
(1) Increase in Abstinence Rate
(2) Increase in Therapy Retention Rate

*Community Reinforcement Approach
** Therapy As Usual

② **불면증** 디지털 치료제

Measurement

디지털 바이오마커 기반 수면패턴 및 증상 모니터링

Phase I

<Smart Phone>

- Non-Contact Monitoring
- Sleep diary automation

Phase II

<3rd Party Wearables>

- WELT DSP Algorithm
- Further automation

Biomarker	Sleep Onset Latency / Cycle & Pattern / Insomnia Severity Index / Sleep Quality (SpO2, HRV, Respiration with 3rd Party Wearables)
Sensors	Accelerometer / Gyroscope / PPG / Microphone

Automation for Accuracy & Improved Usability

WELT-I

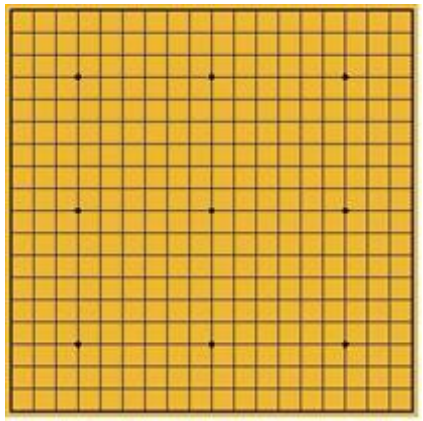
Treatment

WELT 디지털 CBT-I 치료 모듈(PoC Asset)

<Digital CBT-I PoC Product>

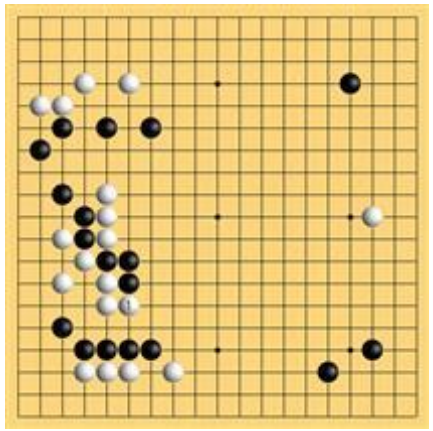
- Interactive Sleep Restriction Therapy
- Personalized Sleep Hygiene Management
- UI/UX Optimization

* 일반적 CBT 형식은 Appendix 참조

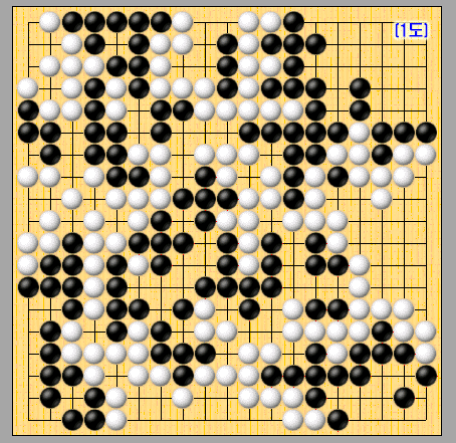


Gene Therapy

+



Digital Therapeutics

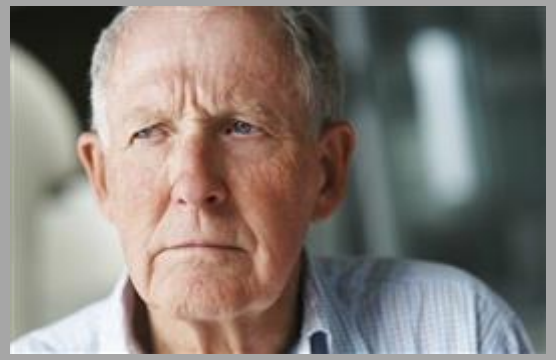


Medication, Operation

Future of Medicine

**“Genetics load the gun,
Lifestyle pulls the trigger”**

As-is



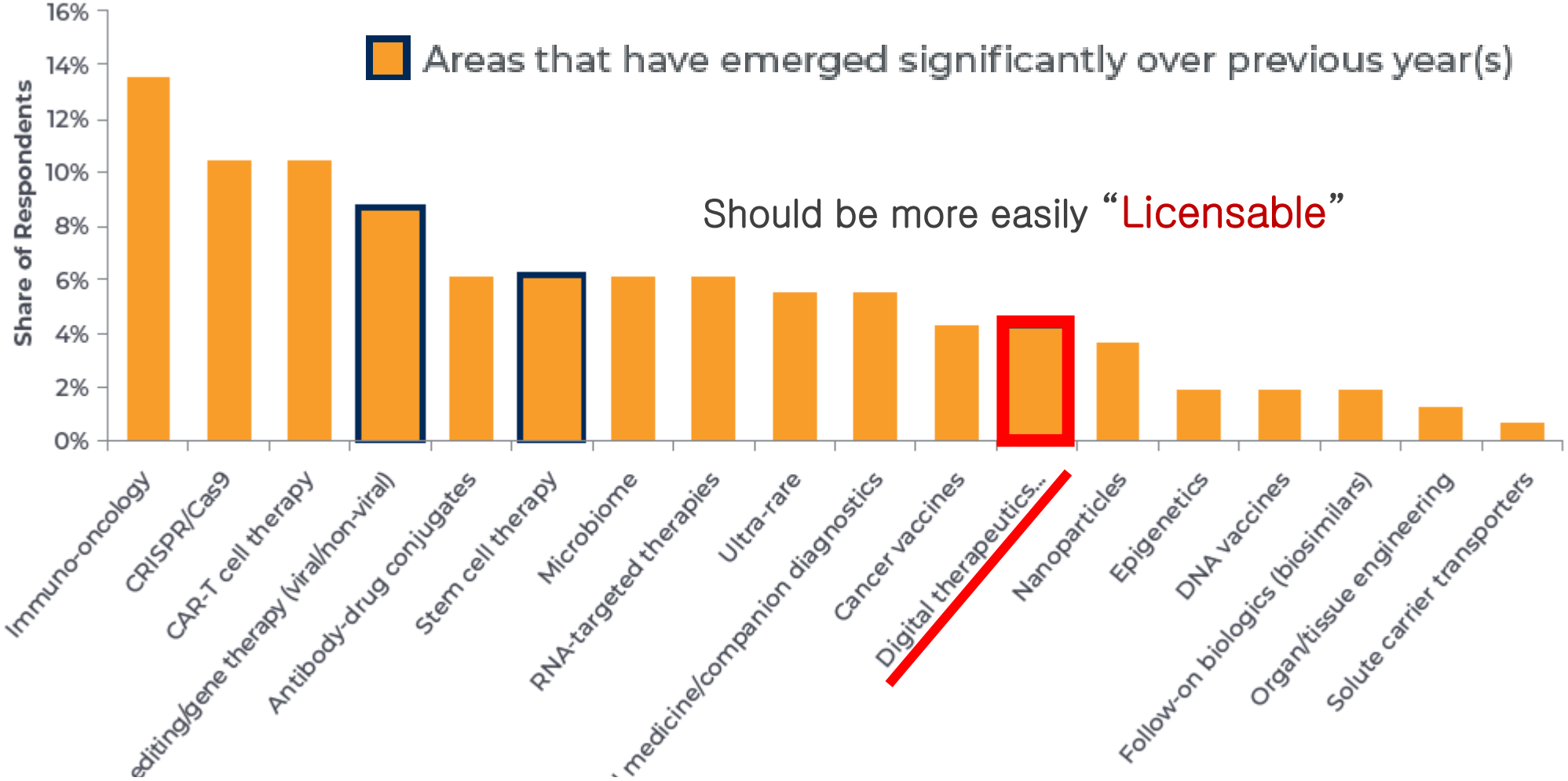
글로벌 제약회사들의 움직임

Digital Biomarkers

Digital Therapeutics

WELT

"Hot" Areas for Licensing in 2019

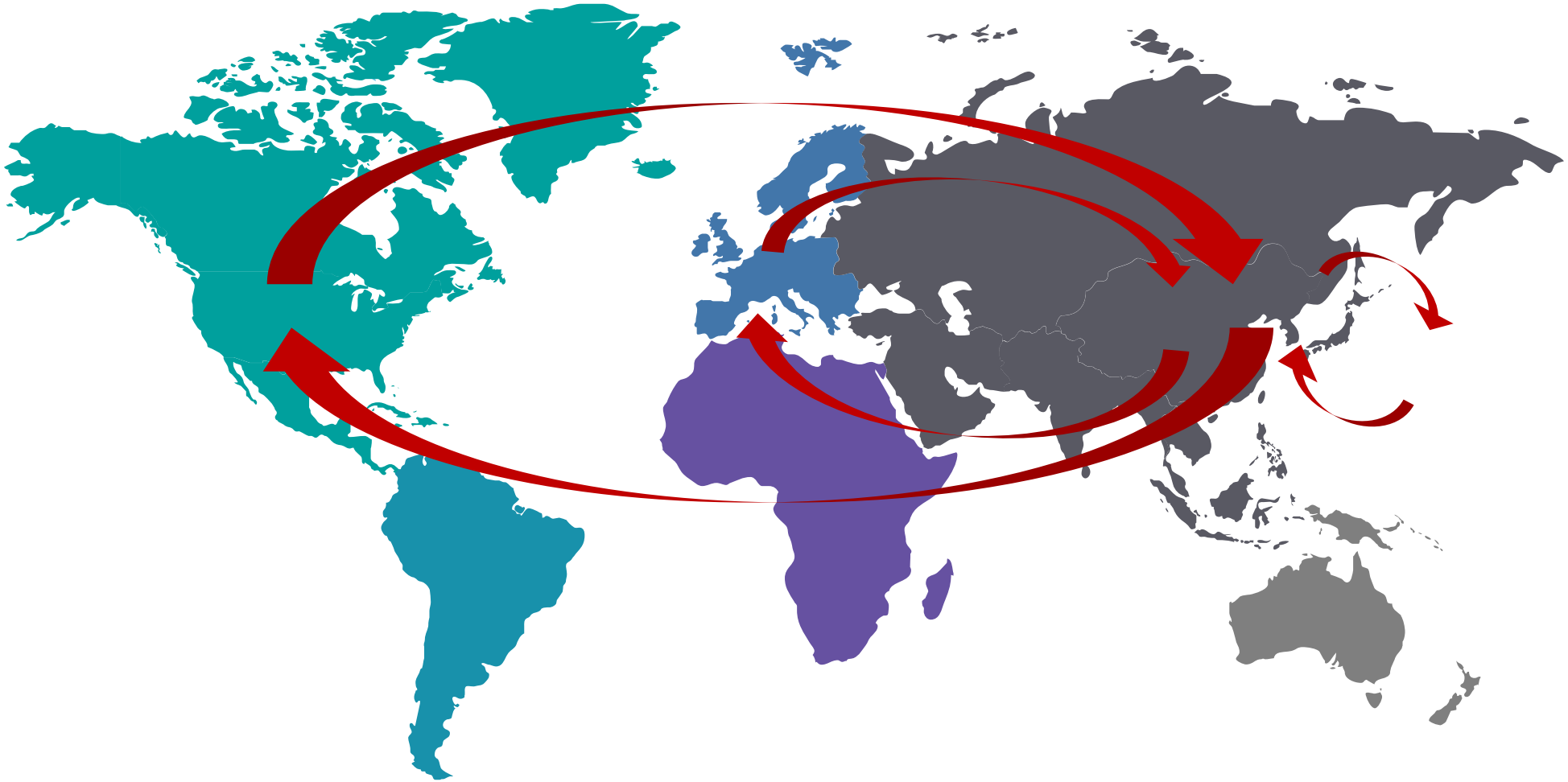


Digital Therapeutics defined as treatments that deliver evidence–based therapeutic interventions to patients driven by high-quality software.

Other Genome Editing / Gene Therapy (Viral / Non-Viral)
Personalized Medicine / Companion Diagnostics

Source: Syneos Health Consulting Dealmakers' Intentions 2019. Includes answers from 51 respondents. Respondents could select multiple areas.

Global Digital Therapeutics network



Digital Therapeutics can help understanding **patients and diseases**.

Real World Data (RWD)

Thank you!

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Digital Therapeutics

+

Digital Biomarker

WELT