Session 2-6

Digital Therapeutics (DTx)

박유랑 조교수 (연세대학교)

[요약문]

디지털 치료제는 의학적 장애나 질병을 예방, 관리, 치료하기 위해 환자에게 근거기반의 치료적 개입을 제공하는 스프트웨어 의료기기를 뜻한다. 디지털 치료제는 주요 목적에 따라 건강상태 취급, 의학적 장애나 질병관리 및 예방, 복약 최적화, 의학적 질병 및 장애 치료 등의 4가지 영역으로 구분된다. 본 발표에서는 이러한 디지털 치료제 자료를 기반으로 기계학습과 인공지능 기법을 적용하여 환자의 예방, 치료, 관리를 수행한 연구에 대해서 공유하고 디지털 치료제의 제한점과 한계를 극복하기 위한 방안에 대해 논의하고자 한다.

[발표자 약력]

2001년 충남대학교 컴퓨터과학과 이학박사

2001년 ~ ETRI 정보보호연구본부 책임연구원

관심분야 : 의료/헬스케어 보안, 융합 보안, CPS/IoT 보안 등

연세대학교 의과대학 YONSEI UNIVERSITY COLLEGE OF MEDICINE DHLab

Digital Therapeutics (DTx)

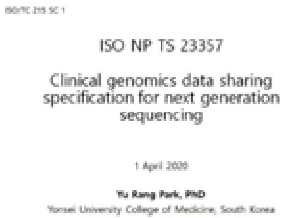
연세대학교 의과대학 의생명시스템정보학교실
박유랑

2020.09.24

Who am I

Research area

- Biomedical data standardization (Genomics and PGHD)
- Digital healthcare, DTx
- Distributed data analysis and platform



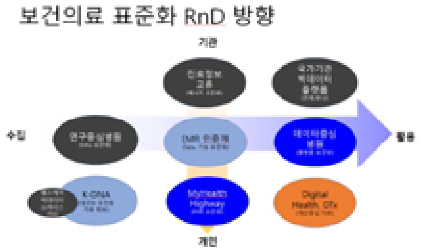
ISO NP TS 23357

Clinical genomics data sharing specification for next generation sequencing

1 April 2020

Yu Rang Park, PhD

Yonsei University College of Medicine, South Korea



Career

Apr, 2019 – Current	Assistant professor Department of biomedical systems informatics, Yonsei university college of medicine
Nov, 2013 – Mar 2018	Research assistant professor Healthcare innovation bigdata center, ASAN Medical Center
May, 2013 – Oct, 2013	Senior researcher Platform technology team, CSP Research Center, Samsung SDS
Mar, 2012 – Apr, 2013	Post-doc (PI: Ju Han Kim, M.D., Ph.D.) Division of Biomedical Informatics, College of Medicine, Seoul National University

Global healthcare challenges

More than **1/3 of people** will be diagnosed with cancer in their lifetime

500+ million people suffer from respiratory diseases

400 million people worldwide have diabetes

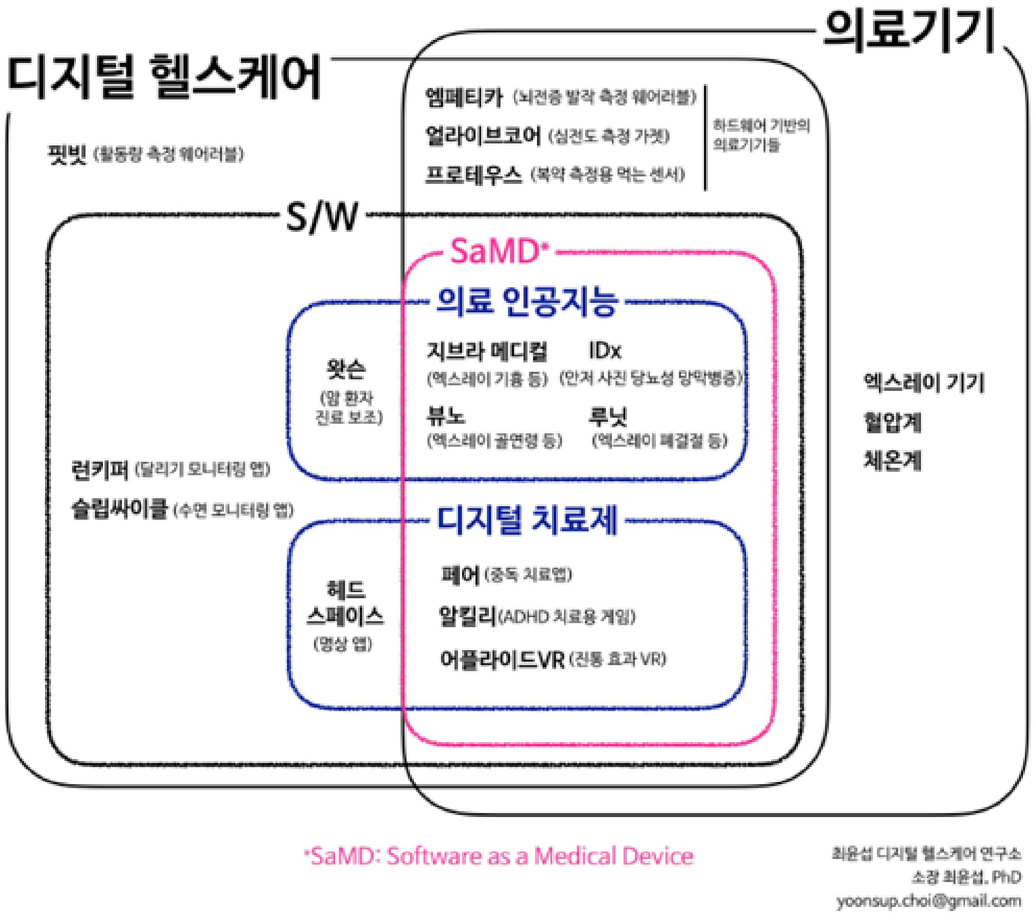
An estimated **1 billion adults** with hypertension

Digital Therapeutics; DTx

Digital therapeutics (DTx) deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a broad spectrum of physical, mental, and behavioral conditions. Digital therapeutics form an independent category of evidence-based products within the broader digital health landscape, and are distinct from pure-play adherence, diagnostic, and telehealth products.

•Enhance and support current medical treatments
•Provide patients, providers, and payers with novel therapy options for unmet medical needs
•Be used independently or in conjunction with other therapies
•Reduce reliance on certain pharmaceuticals or other therapies
•Integrate into medical guidelines and best practices

Source: Digital therapeutics alliance

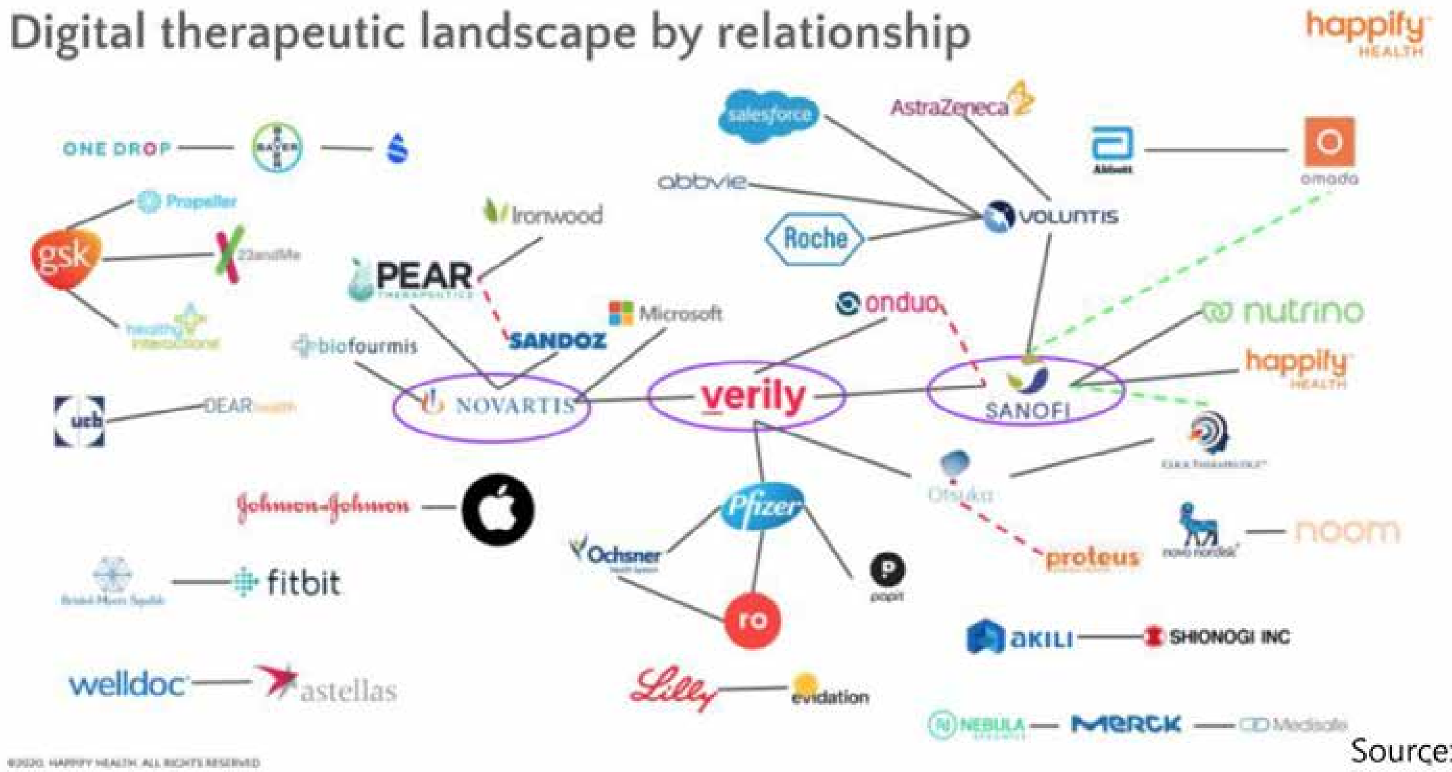


의료기기
디지털 헬스케어
엠페티카 (뇌전증 발작 측정 웨어러블)
얼라이브코어 (심전도 측정 가젯)
프로테우스 (복약 측정용 먹는 센서)
하드웨어 기반의 의료기기들
핏빗 (활동량 측정 웨어러블)
S/W
SaMD*
의료 인공지능
왓슨
(암 환자 진료 보조)
지브라 메디컬
(엑스레이 기흉 등)
IDx
(안저 사진 당뇨성 망막병증)
뷰노
(엑스레이 골연령 등)
루닛
(엑스레이 폐결절 등)
런키퍼 (달리기 모니터링 앱)
슬립싸이클 (수면 모니터링 앱)
디지털 치료제
헤드 스페이스
(명상 앱)
페어 (중독 치료앱)
알킬리(ADHD 치료용 게임)
어플라이드VR (진통 효과 VR)
엑스레이 기기
혈압계
체온계
*SaMD: Software as a Medical Device
최윤섭 디지털 헬스케어 연구소
소장 최윤섭, PhD
yoonsup.choi@gmail.com

< CB insights 선정 디지털 헬스케어 150개 글로벌 스타트업 >

출처 : CB insights, Digital Health 150: The Digital Health Startups Redefining The Healthcare Industry, 2019.10.2.

제약회사와의 제휴



Source: 김치원 원장

Standard of Care내에서 제품 개발
- 기존 약물치료로는 해소되지 않은 ‘행동 ’ 적 요소가 있는 질환을 중심으로

Source: 김치원 원장, 최형진 교수

What medical field can be improved through DTx?

- **DTx for Diabetes**
  - Coach supported weight management program based
  - Hospital PHR based

- **DTx for children**
  - serious game for intellectual disability children
  - Feverish children

Diabetes eHealth(Digital) ecosystem

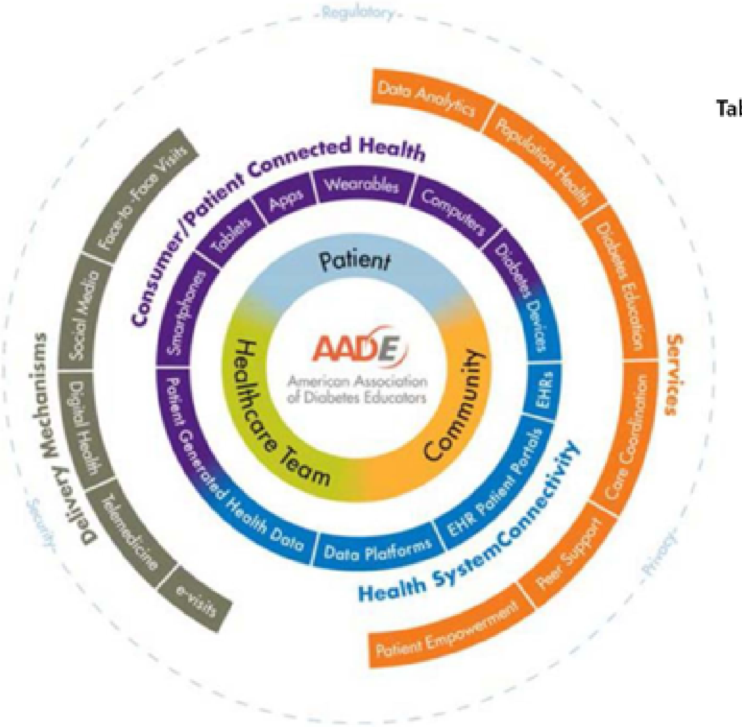


Table. Multiple technology-enabled solutions for diabetes and prediabetes education and care

Delivery methods	*Audience/offerings*	*Third-party attributes*	*Accessibility*	*Metabolic data*
• Self-paced • Group based • **Coaching based on PGHD** • Clinical guidance • Video • Articles • **Interactive tools** • **Phone/app** • Internet	• Prediabetes • Type 1 diabetes • Type 2 diabetes • Peer support community • Analyzed data by report or cloud accessible to the healthcare team • Ability for two-way communication between the patient and healthcare team	• FDA Cleared • Digital therapeutic • ADA recognized DSMES • CDC recognized DPP • ADCES licensed curriculum • DTSec certified	• Open to public • Referral required • Prescription required • Membership required • Integration with individual's local healthcare team	• Glucose • Smart insulin pen doses • Insulin pump data • Heart rate • Blood pressure • Labs *Food and fitness trackers* • **Food** • **Sleep** • **Stress** • **Activity** • Notes • Social determinants • Other

SOUCE: American association of diabetes educators (AADE) 2016 Technology workshop Based on architecture for integrated mobility framework (AIM).

Technology enabled self management feedback loop

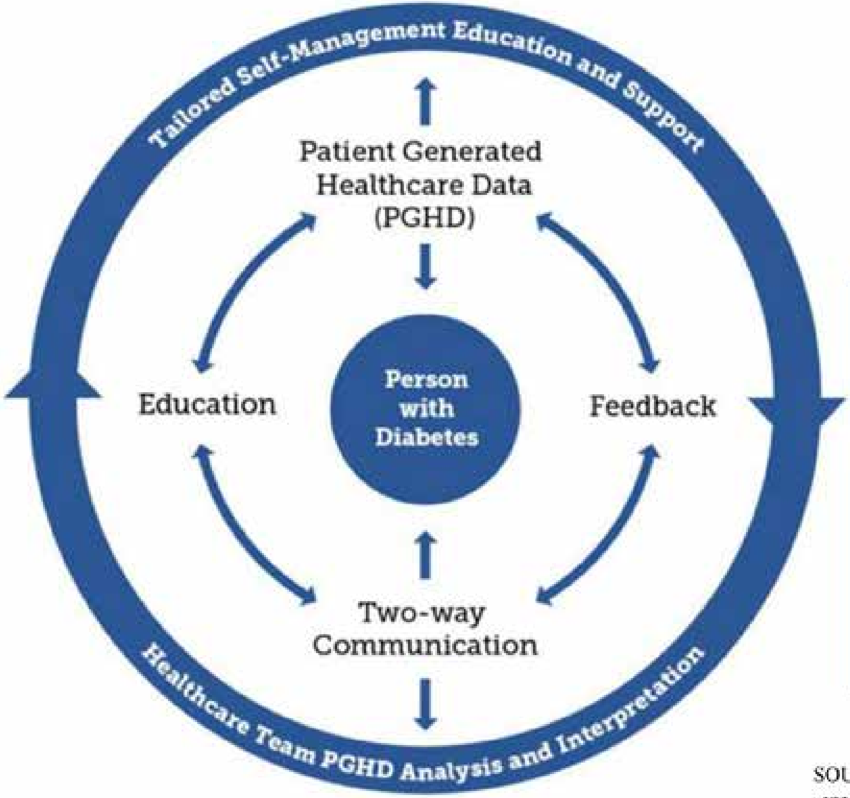


Figure. Critical times to refer to Diabetes self-management education and support

Diabetes Self-management Education and Support for Adults With Type 2 Diabetes: Algorithm of Care

ADA *Standards of Medical Care in Diabetes* recommends all patients be assessed and referred for:

Four critical times to assess, provide, and adjust diabetes self-management education and support			
1 ***At diagnosis***	2 ***Annual*** assessment of education, nutrition, and emotional needs	3 When new ***complicating factors*** influence self-management	4 When ***transitions*** in care occur
When primary care provider or specialist should consider referral:			
❑ Newly diagnosed. All newly diagnosed individuals with type 2 diabetes should receive DSME/S ❑ Ensure that both nutrition and emotional health are appropriately addressed in education or make separate referrals	❑ Needs review of knowledge, skills, and behaviors ❑ Long-standing diabetes with limited prior education ❑ Change in medication, activity, or nutritional intake ❑ HbA_{1c} out of target ❑ Maintain positive health outcomes ❑ Unexplained hypoglycemia or hyperglycemia ❑ Planning pregnancy or pregnant ❑ For support to attain and sustain behavior change(s) ❑ Weight or other nutrition concerns ❑ New life situations and competing demands	Change in: ❑ Health conditions such as renal disease and stroke, need for steroid or complicated medication regimen ❑ Physical limitations such as visual impairment, dexterity issues, movement restrictions ❑ Emotional factors such as anxiety and clinical depression ❑ Basic living needs such as access to food, financial limitations	Change in: ❑ Living situation such as inpatient or outpatient rehabilitation or now living alone ❑ Medical care team ❑ Insurance coverage that results in treatment change ❑ Age-related changes affecting cognition, self-care, etc.

SOUCE: Greenwood DA., et al. (2017) A systematic review of reviews evaluating technology -enabled diabetes self-management education and support. J Diabetes Sci Technology

Technology enabled self management in diabetes

Table. Commonly used technologies to assess daily glucose parameters, experiences, self-care behaviors and context.

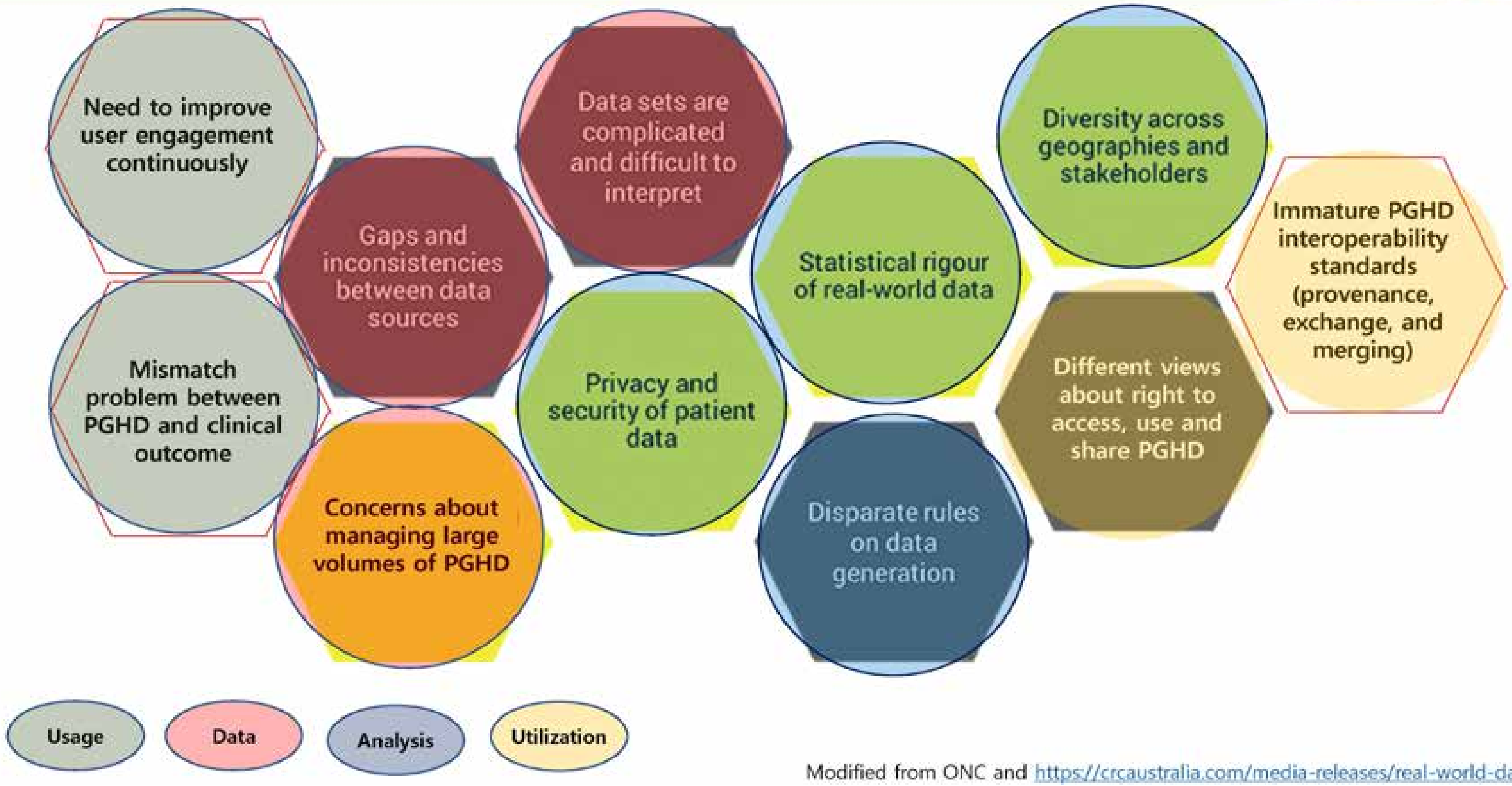
Construct	Measures of interest	Technologies used	Considerations
Glycemic parameters	• Glycemic variability • Time in range • Time in hypo- and hyperglycemia	• Blinded or open continuous glucose monitors	• Can assess variation continuously • Large amount of data • Ideal assessment intervals
Patient-reported outcomes	• Presence of clinical disorders (e.g., depression) • Affect and mood • Motivation and coping	• Smartphone applications • SMS-delivered online surveys • Computer-based surveys • Audio recording devices,	• Reduces bias, more ecologically valid • Measures are often unvalidated • Burden and ease of use for participants
Context			
Medication adherence			

Construct	Measures of interest	Technologies used	Considerations
Physical activity	• Steps taken • Heart rate • Heart rate variability • Sedentary behavior	• Smartphone applications (SR) • SMS-delivered online surveys (SR) • Wearable wristbands	• Many technology options • Accuracy of measures unclear • Large amount of data (e.g., every minute)
Diet and food choices	• Calories consumed • Carbohydrates consumed • Protein and fat consumed • Food choices (e.g., soda and vegetables)	• Smartphone applications (SR) • SMS-delivered online surveys (SR) • Cameras • CGM monitors (excursions)	• Large amount of data • Often requires additional coding (e.g., images) • Selective or incomplete use of monitoring technology can often be a problem
Sleep	• Hours slept • Time in REM • Number of awakenings • Sleep quality	• Smartphone applications (SR) • SMS-delivered online surveys (SR) • Wearable wristbands	• Wearables allow for objectively quantifying sleep, though sleep is assessed indirectly, high noise

REM, Rapid eye movement; SR, self-report; SMS, short message service.

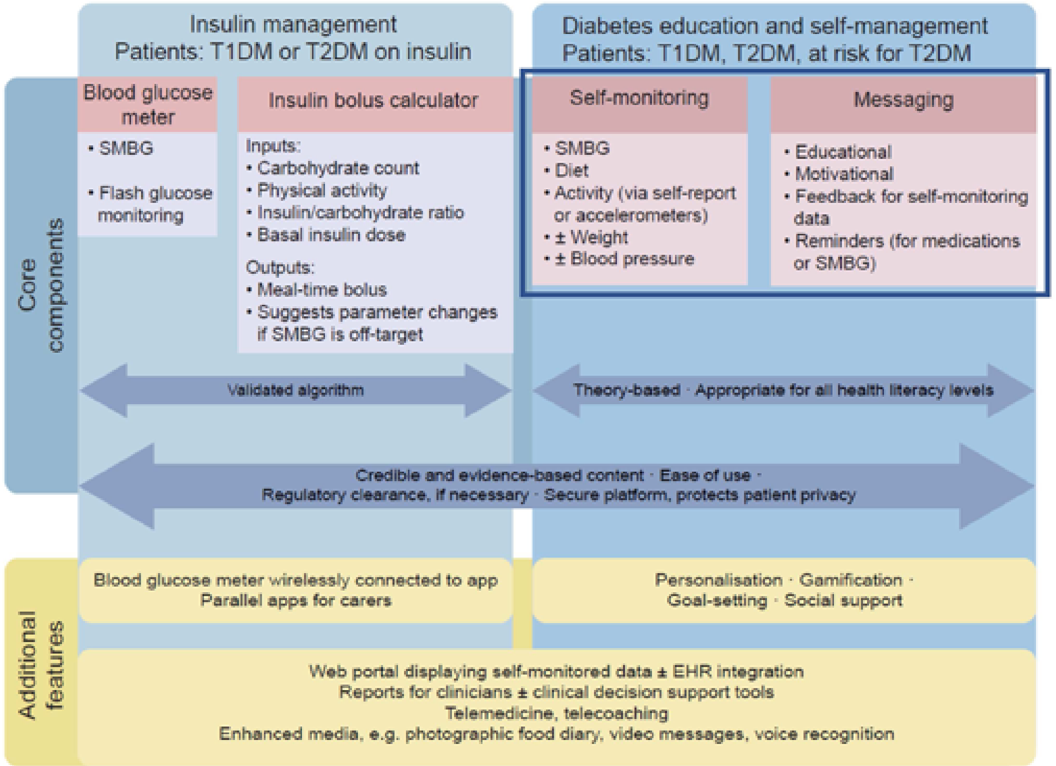
SOUCE: David C. Klonoff (2020) Diabetes digital health. Elsevier

Limitation and challenges with PGHD



Modified from ONC and https://crcaustralia.com/media-releases/real-world-data/

Key features of mHealth interventions for diabetes



- mHealth interventions for diabetes are heterogeneous and clinical effects are generally modest
- Barriers to adoption include cost, sustainability and integration with healthcare systems
- mHealth has potential to expand access to healthcare in underserved populations and to deliver precision medicine
- More work is needed to assess which features promote clinical efficacy and patient engagement
- Future work in diabetes should focus on medication adherence and lifestyle modifications
- Closed-loop systems may replace the need for insulin management mHealth tools

SOURCE: Shan et al (2019) Diabetologia. Digital health technology and mobile devices for the management of diabetes mellitus: state of art.

Reality check for DTx in diabetes management

Hospital based

1.Park YR, et al. Managing Patient-Generated Health Data Through Mobile Personal Health Records: Analysis of Usage Data. JMIR Mhealth Uhealth 2018;6(4):e89

2. Park YR, et al. The Use of Mobile Personal Health Records for Hemoglobin A1c Regulation in Patients With Diabetes: Retrospective Observational Study. J Med Internet Res 2020;22(6):e15372

Person based

1.Kim HH, et al. Weight loss and behavior pattern in relation to goal setting in short-term mobile diet programs: an observational cohort study using a single mobile application. (under review)

2. Kim HH, et al. Identification of weight loss trajectories and their factors in a 16-week mobile app intervention: a retrospective observational study. (under review)

3. Kim HH. et al. Development of prediction model for weight change in obesity management mobile app: using interpretable AI with attention mechanism. (in preparation)

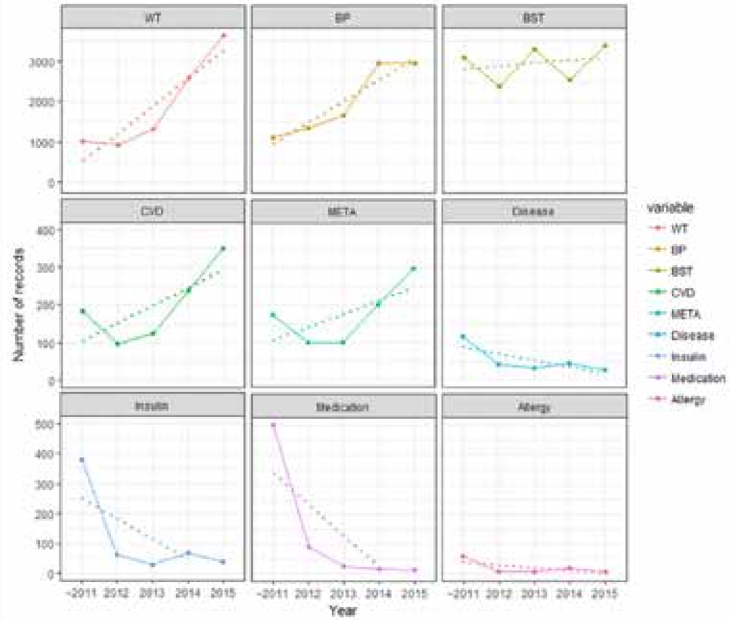
4. Kwon HW, et al. Development of Prediction Model for Customer Churn with Lifelog Data in Mobile Healthcare Application : Retrospective Study. (in preparation)

Which person continuously use the DTx?

Older patient with chronic disease

Table 3. Characteristics of patients who used patient-generated health data functions in health and risk management continuously ("Yes") versus those who did not ("No").

Variables/Categories	Health management[a] (n=3472)				Risk management[b] (n=754)			
	Yes (n=94)	No (n=3378)	P value[c]	P value[d]	Yes (n=50)	No (n=704)	P value[c]	P value[d]
Age (years), mean (SD)	51.81 (12.07)	43.79 (15.37)	<.001	N/A[e]	46.98 (11.67)	47.92 (11.24)	.58	N/A
Sex, n (%)			<.001	N/A			.75	N/A
Male	76 (81)	2101 (62.20)			35 (70)	470 (66.8)		
Female	18 (19)	1277 (37.80)			15 (30)	234 (33.2)		
Distance to the hospital, n (%)			.41	N/A			.26	N/A
Short	35 (37)	1103 (32.65)			12 (24)	231 (32.8)		
Long	59 (63)	2275 (67.34)			38 (76)	473 (67.2)		
Disease classification[f], n (%)								
Cancer (C00-C97)	11 (12)	606 (17.94)	.14	.08	8 (16)	99 (14.1)	.87	.63
Diabetes (E10-E14)	12 (13)	122 (3.61)	<.001	<.001	2 (4)	29 (4.1)	>.99	.96
Cardiovascular disease (I20-I51)	4 (4)	90 (2.66)	.33	.55	2 (4)	19 (2.7)	.64	.57
Cerebrovascular disease (I60-I69)	4 (4)	38 (1.12)	.03	.03	0 (0)	14 (2.0)	.62	.98
Chronic lower respiratory disease (J40-J47)	1 (1)	15 (0.44)	.36	.35	0 (0)	2 (0.3)	>.99	.98
Liver disease (K70-K76)	14 (15)	299 (8.85)	.08	.42	4 (8)	72 (10.2)	.79	.59
Chronic disease	39 (42)	1070 (31.68)	.08	.27	15 (30)	218 (31.0)	>.99	.92
Type of hospital visit, n (%)								
Emergency room	59 (62)	1811 (53.36)	.15	N/A	30 (59)	371 (52.1)	.43	N/A
Outpatient department	94 (98)	3,334 (98.70)	.68	N/A	49 (96)	699 (98.2)	.264	N/A
Hospitalization	76 (79)	2,689 (79.60)	>.99	N/A	42 (82)	544 (76.4)	.423	N/A

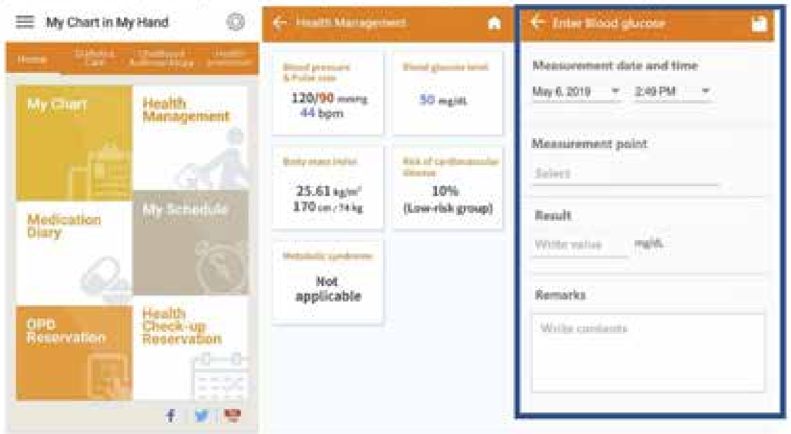


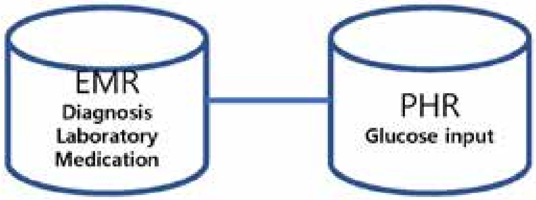
Park YR, Lee Y, Kim JY, Kim J, Kim HR, Kim YH, Kim WS, Lee JH. Managing Patient-Generated Health Data Through Mobile Personal Health Records: Analysis of Usage Data. JMIR Mhealth Uhealth 2018;6(4):e89

How can DTx help patients?

Management of diabetes

Figure 1. Screenshots of My Chart in My Hand version 2.0. Inputting data in the sugar function follows from the home page to Enter Blood Glucose.





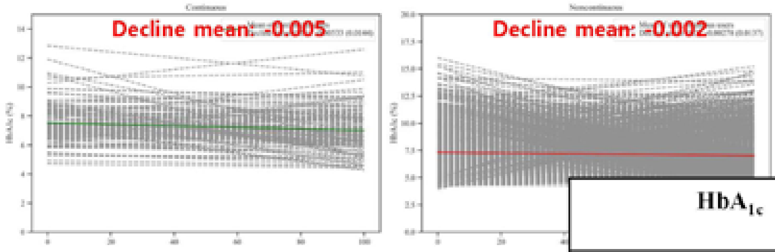
Variables	Users: Continuous (n=133)	Users: Noncontinuous (n=7320)	Total (N=7453)	P value[a]
Age (years), mean (SD)	53.59 (9.89)	57.58 (11.95)	57.51 (11.92)	<.001
Sex, n (%)				<.001
Male	110 (82.7)	4859 (66.37)	4969 (66.67)	
Female	23 (17.3)	2461 (33.62)	2484 (33.33)	
Sugar function				
Data generated by users, n (%)	133 (100.0)	289 (3.95)	422 (5.66)	<.001
Total data generated, n	22,350	1345	23,695	—[b]
Individually generated data				<.001
Mean (SD)	168.0 (204.0)	0.2 (1.8)	3.2 (35.1)	
Median (IQR)	97 (43-186)	0 (0-0)	0 (0-0)	
Diabetes calendar function				
Data generated by users, n (%)	133 (100.0)	297 (4.06)	430 (5.77)	<.001
Total data generated, n	16,407	1453	17,860	—
Individually generated data				<.001
Mean (SD)	123.4 (143.3)	0.2 (4.0)	2.4 (25.4)	
Median (IQR)	67 (35-145)	0 (0-0)	0 (0-0)	
HbA_{1c}[c], mean (SD)				
Number of measurements	12.44 (6.90)	11.90 (6.82)	11.92 (6.82)	.38
Measure frequency	0.011 (0.010)	0.009 (0.005)	0.009 (0.005)	.007
Measurement days	1254 (461)	1336 (445)	1335 (446)	.04
Measurement days before MCMH[d] version 2.0 start	546 (348)	712 (377)	710 (377)	<.001
First HbA_{1c} measurement ≥6.5%, n (%)	111 (83.4)	5716 (78.09)	5827 (78.18)	.14
First HbA_{1c} measurement, mean (SD)	7.86 (1.78)	7.51 (1.62)	7.51 (1.62)	.01
DCSI[e], mean (SD)	1.17 (1.65)	1.15 (1.64)	1.15 (1.64)	.99
Complications, n (%)				
Retinopathy or ophthalmic	31 (23.3)	1516 (20.71)	1547 (20.75)	.46
Nephropathy	13 (9.8)	765 (10.45)	778 (10.44)	.80
Neuropathy	23 (17.3)	1267 (17.31)	1290 (17.31)	>.99
Cerebrovascular	20 (15.0)	950 (13.00)	970 (13.01)	.48
Cardiovascular	16 (12.0)	1366 (18.7)	1382 (18.54)	.05
Peripheral vascular disease	1 (0.8)	59 (0.8)	60 (0.81)	.94
Metabolic complications	1 (0.8)	37 (0.5)	38 (0.51)	.69

Park YR, et al. The Use of Mobile Personal Health Records for Hemoglobin A1c Regulation in Patients With Diabetes: Retrospective Observational Study. J Med Internet Res 2020;22(6):e15372

How can DTx help patients?

Management of diabetes

Figure 3. Hemoglobin A_{1c} (HbA_{1c}) patterns (decline, r-squared value, and SD) of continuous and noncontinuous users. The x-axis is the percentage of days past from the first HbA_{1c} measurement compared with the period between the first and last HbA_{1c} measurements. The dashed lines are the HbA_{1c} decline of each patient. The slope and y-axis intercept of the continuous lines indicates the mean of slope and y-axis of patients, respectively.



HbA_{1c}	Continuous user (n = 133)	Non-continuous user (n = 7320)	*P* value
First measurement <6.5%			
last measurement			
<6.5%, n(%)	15 (11.3)	1040 (14.21)	.34
≥6.5%, n(%) [Worse than before]	7 (5.3)	564 (7.70)	.29
First measurement ≥6.5%			
Last measurement			
<6.5%, n(%) [Better than before]	38 (28.6)	564 (7.70)	.01
≥6.5%, n(%)	73 (54.9)	4278 (58.44)	.41

Park YR, et al. The Use of Mobile Personal Health Records for Hemoglobin A1c Regulation in Patients With Diabetes: Retrospective Observational Study. J Med Internet Res 2020;22(6):e15372

Noom coach – weight management

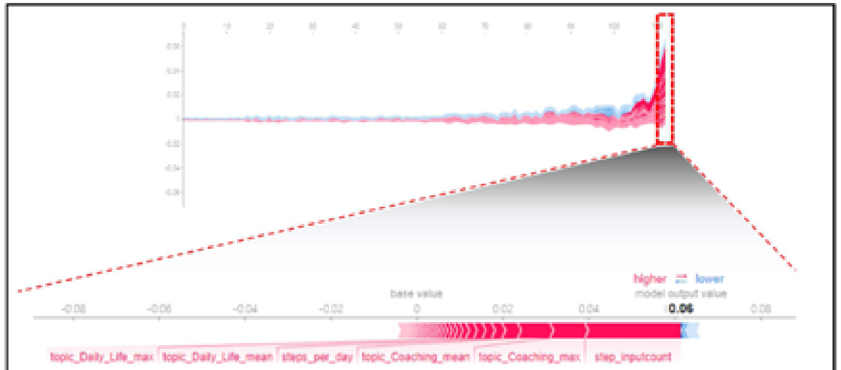
- Noom, the weight-loss and personalized meal-planning service.
- More than 45 million users, The best Healthcare app in App store, $200 million Sales in 2019.

Diet Exercise Management | Providing Health care contents | Interactive Coaching Message | Record and Analysis of weight/meal

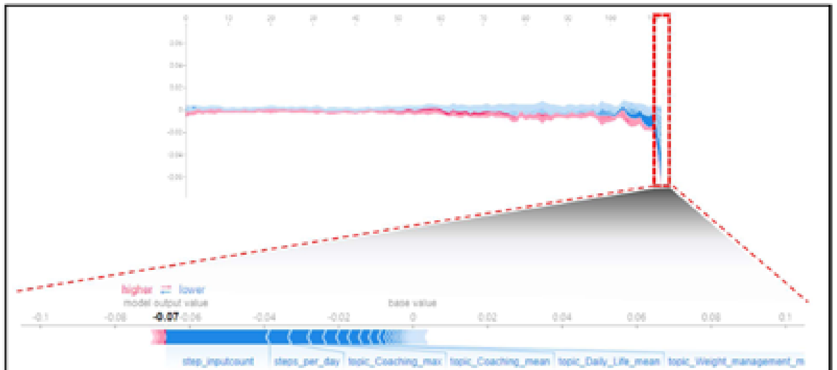
Which person continuously use the DTx?

Interpretation with GradientExplainer

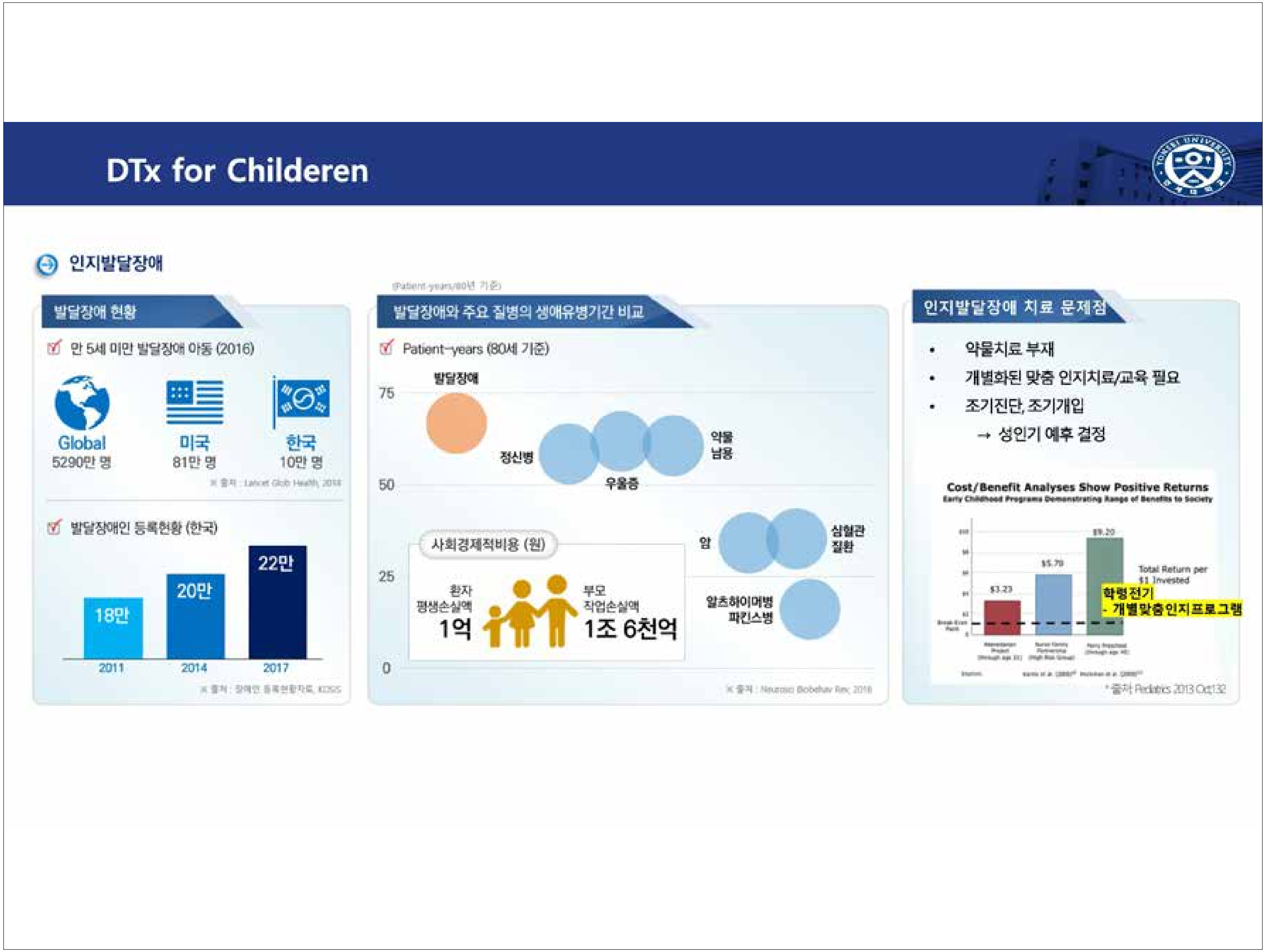
The plots above showed how the variables at each time point affected the results of the churn prediction model. The red areas are the variables that influenced the model's **final predicted values being high**, and the blue areas represent the attributes that affected the model's **final predicted values being low**. Overall, the attributes of the variables appear larger time point of churn and retain.



Churn users' Attributions of Variables at Last day (112th day)



Retain users' Attributions of Variables at Last day (112th day)


DTx for Childeren
인지발달장애
발달장애 현황
만 5세 미만 발달장애 아동 (2016)
Global
5290만 명
미국
81만 명
한국
10만 명
발달장애인 등록현황 (한국)
18만
20만
22만
2011
2014
2017
발달장애와 주요 질병의 생애유병기간 비교
Patient-years (80세 기준)
75
50
25
0
발달장애
정신병
우울증
약물
남용
암
심혈관
질환
알츠하이머병
파킨스병
사회경제적비용 (원)
환자
평생손실액
1억
부모
직업손실액
1조 6천억
인지발달장애 치료 문제점
• 약물치료 부재
• 개별화된 맞춤 인지치료/교육 필요
• 조기진단, 조기개입
→ 성인기 예후 결정
Cost/Benefit Analyses Show Positive Returns
Early Childhood Programs Demonstrating Range of Benefits to Society
$3.23
$5.70
$9.20
Total Return per
$1 Invested
학령전기
- 개별맞춤인지프로그램
* 출처 Pediatrics 2013 Oct132

DTx for ADHD (US FDA approval)

FDA NEWS RELEASE

FDA Permits Marketing of First Game-Based Digital Therapeutic to Improve Attention Function in Children with ADHD

For Immediate Release: June 15, 2020

Today, the U.S. Food and Drug Administration (FDA) permitted marketing of the first game-based digital therapeutic device to improve attention function in children with attention deficit hyperactivity disorder (ADHD). The prescription-only game-based device, called EndeavorRx, is indicated for pediatric patients ages 8 to12 years old with primarily inattentive or combined-type ADHD who have demonstrated an attention issue. EndeavorRx is indicated to improve attention function as measured by computer-based testing and is the first digital therapeutic intended to improve symptoms associated with ADHD, as well as the first game-based therapeutic granted marketing authorization by the FDA for any type of condition. The device is intended for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.

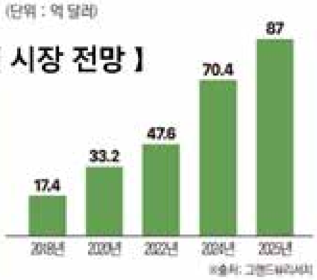
"The EndeavorRx device offers a non-drug option for improving symptoms associated with ADHD in children and is an important example of the growing field of digital therapy and digital therapeutics," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "The FDA is committed to providing regulatory pathways that enable patients timely access to safe and effective innovative digital therapeutics."

ADHD is a common disorder that begins in childhood, affecting approximately 4 million children ages 6-11. Symptoms include difficulty staying focused and paying attention, difficulty controlling behavior, and very high levels of activity. According to the Centers for Disease Control and Prevention, diagnosis of ADHD should be conducted by a trained health care professional and follow an evaluation of symptoms or pattern of symptoms, such as inattention, hyperactivity, and impulsivity that interfere with functioning or development.

The FDA reviewed data from multiple studies in more than 600 children, including studies that

【 ADHD 아동 대상 DTx 】
- 집중력 증가 효과 검증

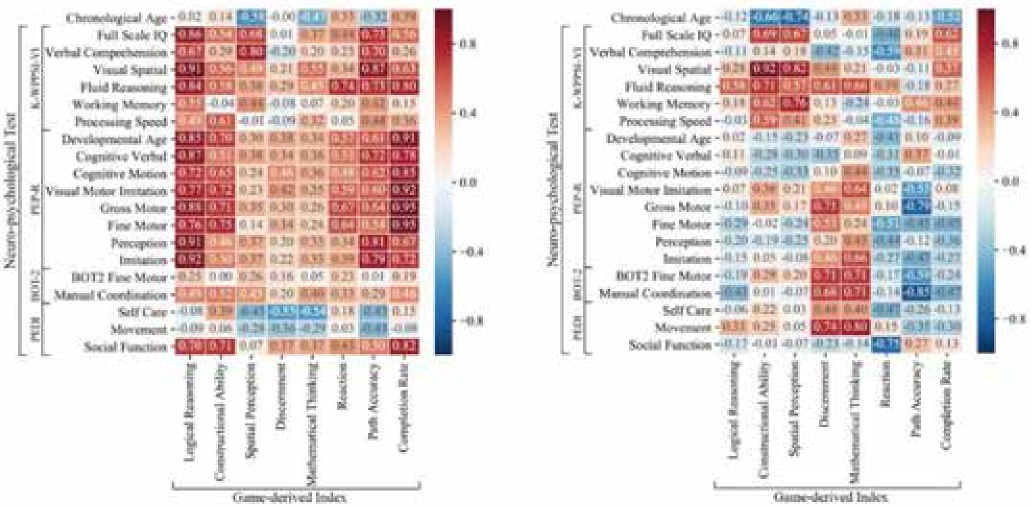
【 디지털치료제 시장 전망 】



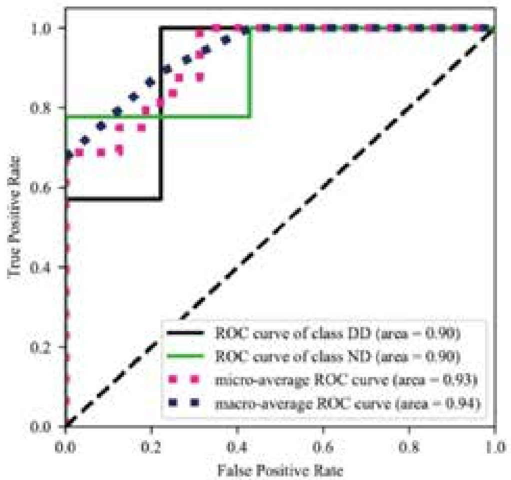
How can DTx help patients?

Early detection

to distinguish between **children with heterogeneous developmental disabilities and those with normal development** using Game Derived Index



(a) Normal Developing Group (B) Developmental Disability Group



(A) ROC curves of GDI−based Model

Figure 3. Correlation matrix for the game-derived index and neuro-psychological tests of normal development and developmental disability group. Bang C, Nam Y, Ko EJ, Lee W, Kim B, Choi Y, Park YR. A serious game-derived index for detecting children with heterogeneous developmental disabilities: A randomized clinical trial. JMIR Preprints. 04/06/2019:14924 (under review)

How can DTx help patients?

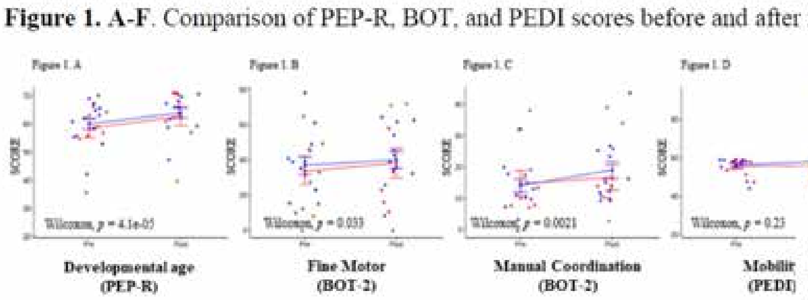
Treatment

to identify the **effect of serious game on cognitive improvement** in children with developmental disabilities.

Outcome	Intervention (n=21)		P-value (Wilcoxon signed rank test)	Control (n=18)		P-value (Wilcoxon signed rank test)	Median difference between groups* (Mann-Whitney U test)		
	Pre test (T1)	Post test (T2)		Pre test (T1)	Post test (T2)		Median difference	95% CI	P-value
K-WPPSI-VI									
Full Scale IQ	92.05 (26.84)	105.24 (27.10)	0.11	96.83 (18.81)	104.00 (20.53)	0.37	9.00	(4.00, 13.00)	0.0005
Verbal comprehension	96.52 (26.46)	108.05 (25.63)	0.15	94.33 (21.02)	101.89 (20.27)	0.06	5.00	(-1.0, 10.00)	0.1336
Visual Spatial	92.43 (24.70)	102.90 (24.84)	0.12	92.11 (21.26)	98.11 (21.61)	0.17	3.00	(-1.00, 9.00)	0.1599
Fluid Spatial	90.24 (21.92)	101.71 (22.51)	0.06	107.67 (22.10)	108.89 (20.67)	0.26	5.00	(0.00, 10.00)	0.0796
Working Memory	105.95 (24.04)	109.76 (21.91)	0.60	93.78 (17.45)	98.11 (16.18)	0.78	3.00	(-1.00, 6.00)	0.1944
Processing Speed	89.19 (18.66)	98.10 (20.32)	0.14	96.72 (20.74)	101.44 (21.01)	0.40	3.00	(0.00, 9.00)	0.0254

* Estimated between-group difference (intervention – control) after intervention (Post-test, T2), for pre-test (T1) values

Figure 1. A-F. Comparison of PEP-R, BOT, and PEDI scores before and after intervention

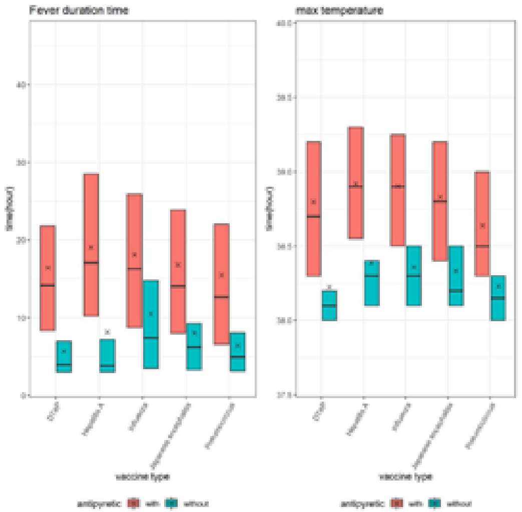


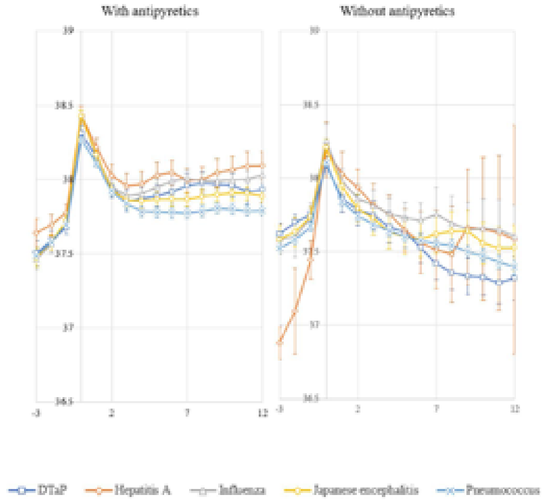
Kim HH, An JI, KIM B, Park YR. The Effect of Serious Game on Cognitive Improvement in Children with Developmental disabilities: A Randomized Clinical Trial. AMIA 2020 Informatics Submit (under review)

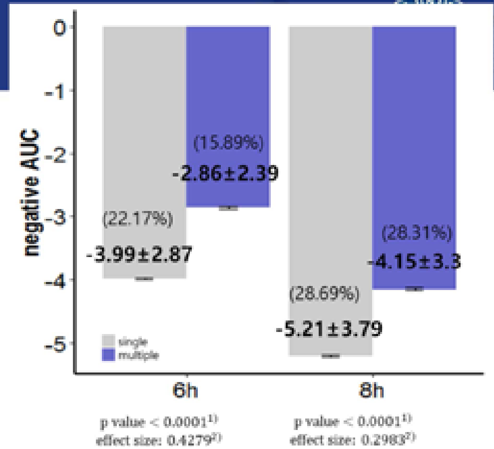
How can DTx help patients?

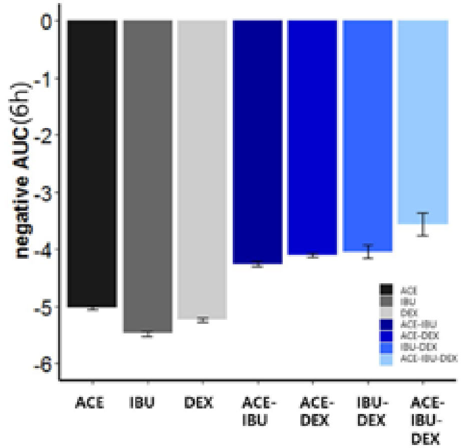
Management

to identify **thermal patterns according to antipyretic drug and vaccination** in patient generated health data



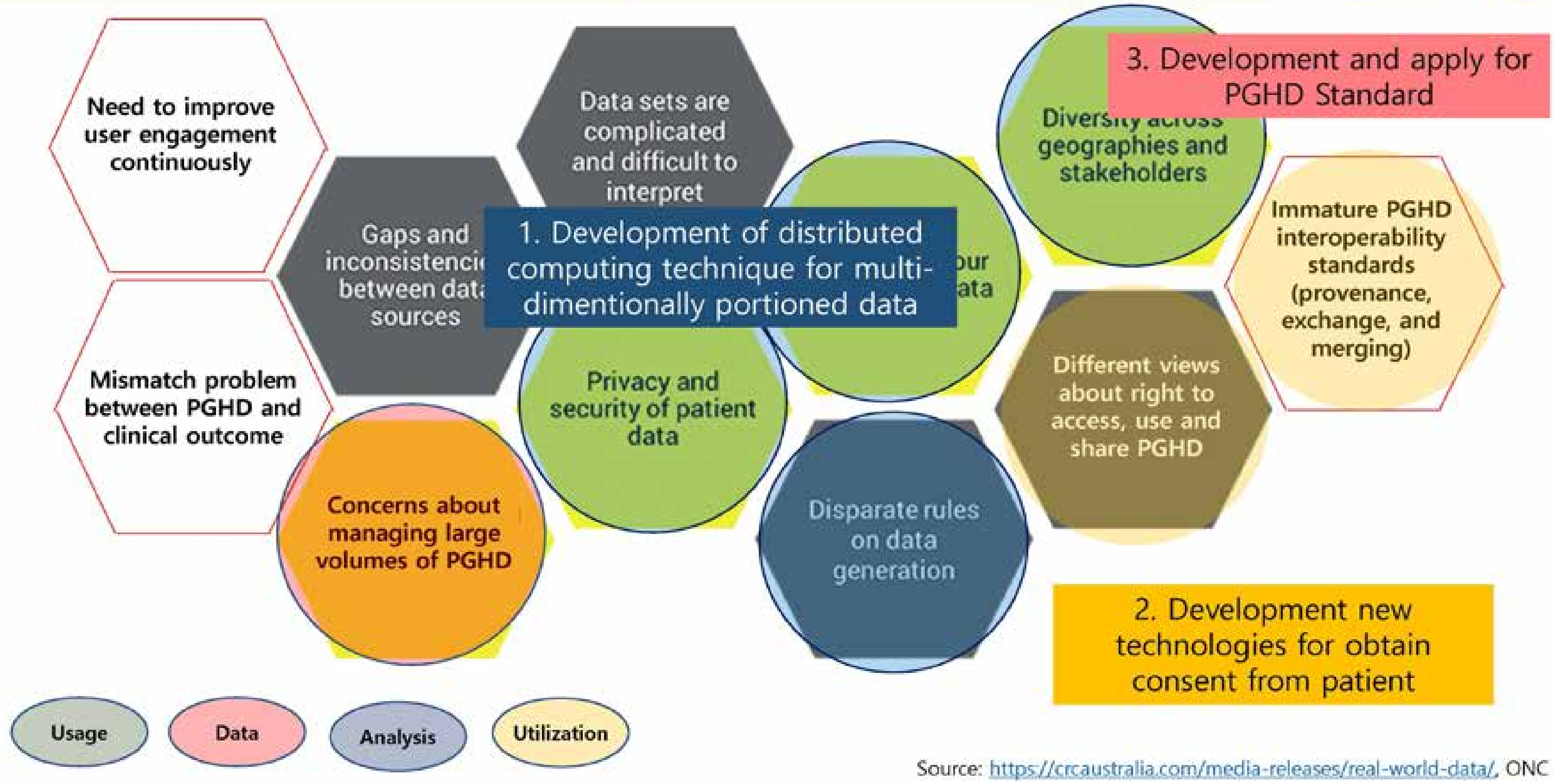






Ahn SH*, Zhiang J*, Kim H, Chang S, Shin J, Kim M, Lee Y, Lee JH, Park YR. Postvaccination Fever Response Rates in Children Derived Usir the Fever Coach Mobile App: A Retrospective Observational Study. JMIR Mhealth Uhealth 2019;7(4):e12223
Park YR*, Kim H*, Park JA, Ahn SH, Chang S, Shin JW, Kim M, Lee JH. Comparative analysis of antipyretic effects between single and combined antipyretic therapy in children using real-world big data collected with a mobile application "Fever coach". (in preparation)

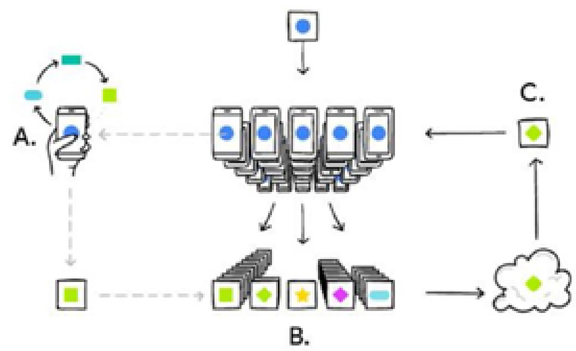
Limitation and challenges with PGHD



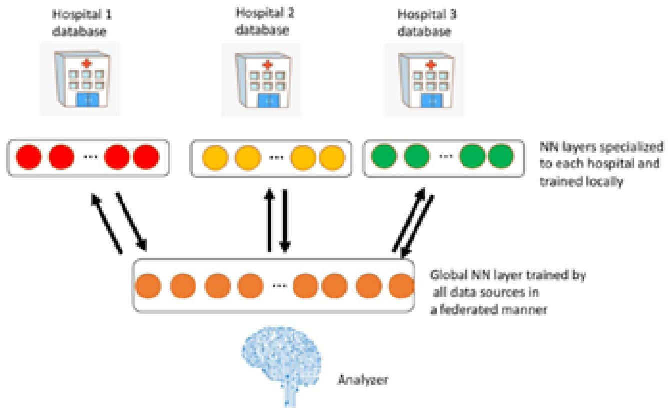
Source: https://crcaustralia.com/media-releases/real-world-data/, ONC

Development of distributed computing technique

- **Cross Device**: On mobile phone and edge application
- **Cross Silo**: Only a small number of relatively reliable clients



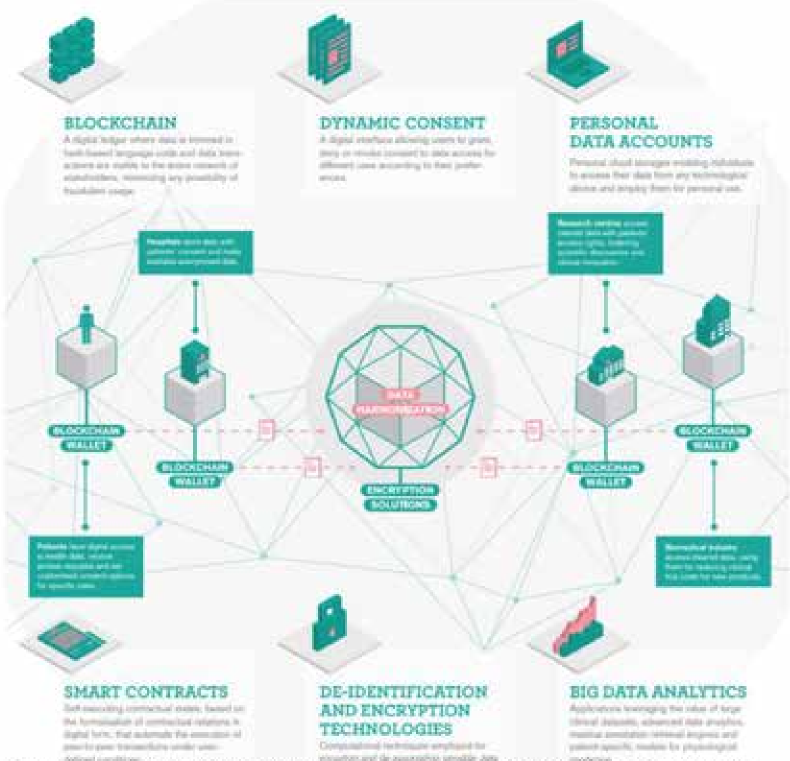
https://www.googblogs.com/federated-learning-collaborative-machine-learning-without-centralized-training-data/



Liu, Dianbo, et al. "FADL: Federated-Autonomous Deep Learning for Distributed Electronic Health Record." arXiv preprint arXiv:1811.11400 (2018).

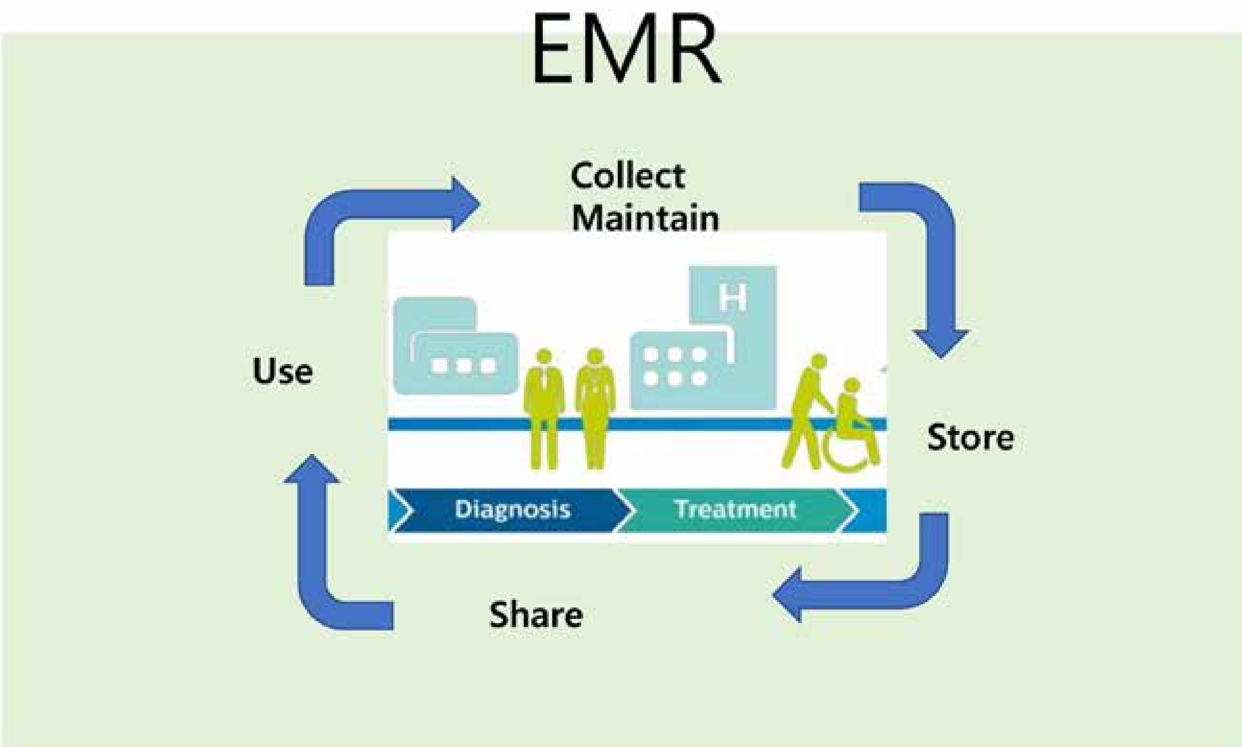
Develop new consent and standards to PGHD utilization

- Consent technology
  - Tiered consent
  - Dynamic consent
- Data standard for PGHD
  - Consistent guideline for generating PGHD
  - Data specification
  - Use case

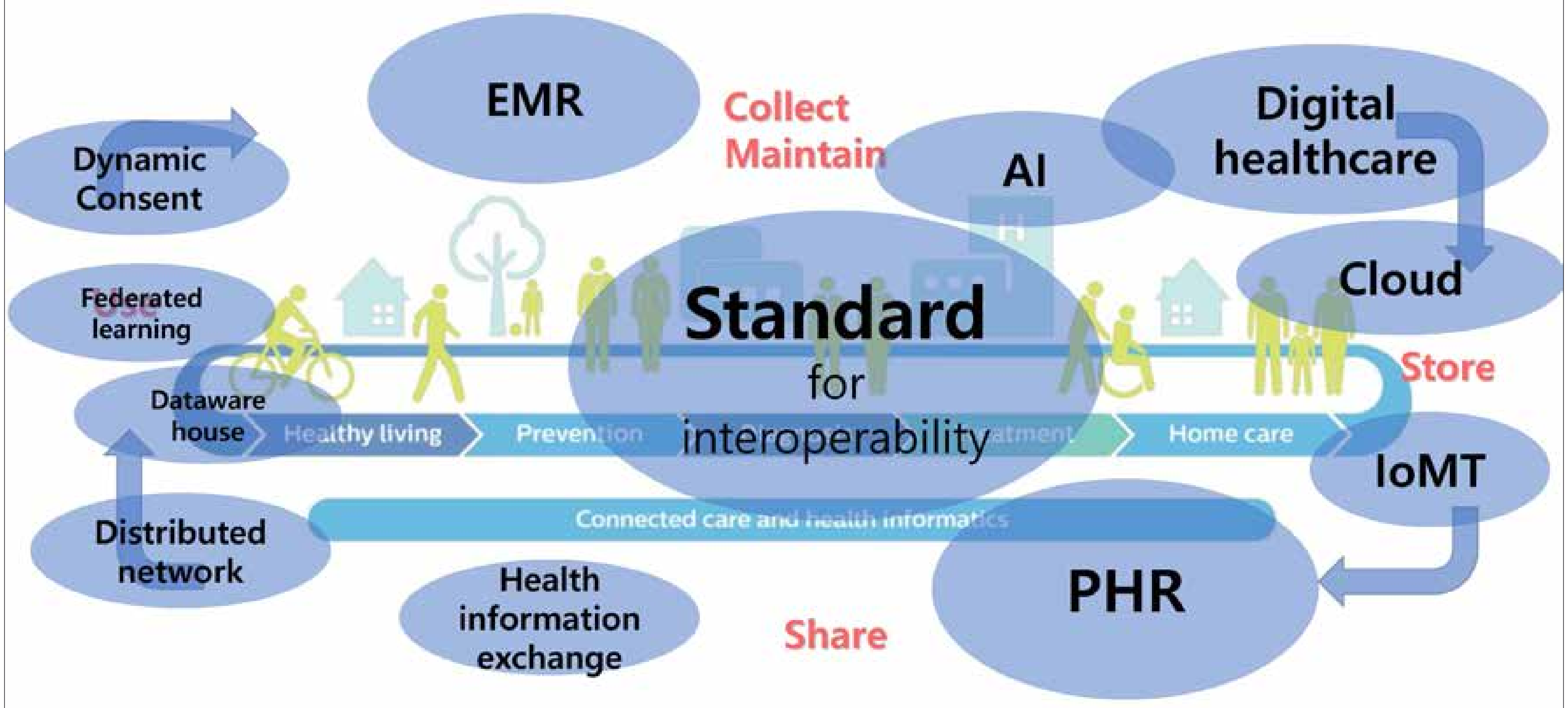


My Health My Data (MHMD) A new paradigm in healthcare data privacy and security. Poster. 1 Nov 2016.

Medical informatics lifecycle

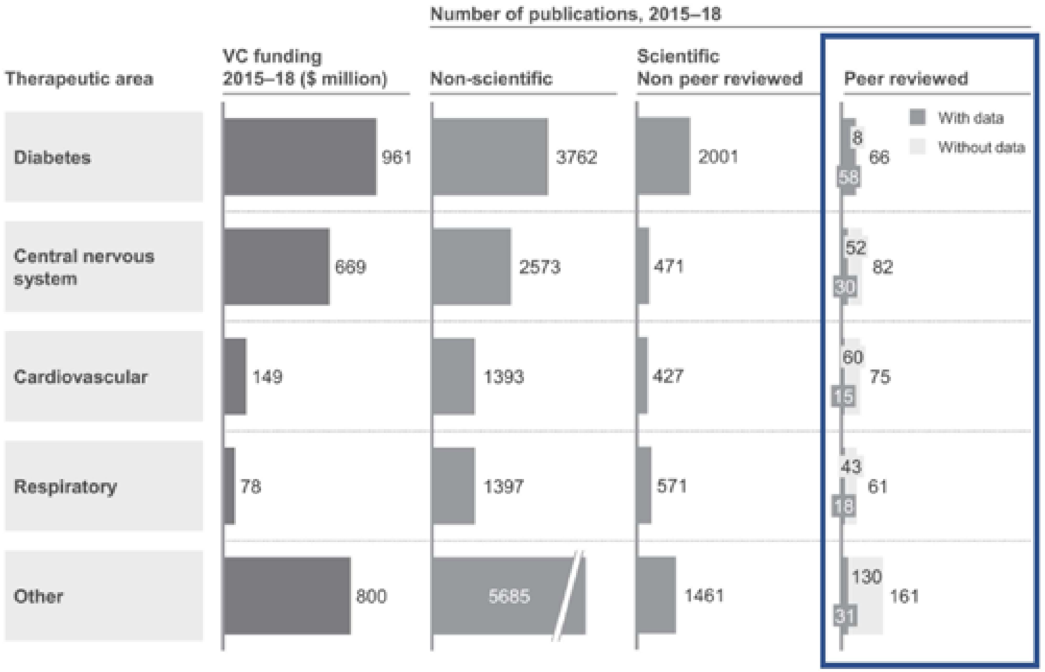


Development and apply for PGHD Standard



Are digital health poised to become mainstream in diabetes?

An overview of digital health funding and publishing by therapeutic area.



SOUCE: David C. Klonoff (2020) Diabetes digital health. Elsevier

Are digital health poised to become mainstream in diabetes?

- Digital health, although nascent, have shown great promise in addressing the burden of chronic disease but are still struggling for widespread adoption.
- The level of robust clinical evidence generated to support these technologies is limited, with higher volumes and quality required to differentiate them from “health and wellness” app.
- Current business models will need to evolve in line with change in the healthcare ecosystem, while other external enablers, such as regulatory clarity, demand form health systems, an improvement in underlying technologies, and sustained investment, will need to be addressed to support mainstream adoption.

SOUCE: David C. Klonoff (2020) Diabetes digital health. Elsevier

Thank you

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https://www.dhlab.org/