

Top Digital Therapeutic Highlights of 2019 So Far

Updated

Dear Colleagues,

With an influx of exciting partnership, reimbursement contracts and regulatory breakthroughs, it is clear **2019 has been a ground-breaking year for the digital therapeutics industry.**

In order to celebrate the industry's collective achievements, here at the DTx Team, we've **collated our top 20 favourite pieces of DTx highlights and industry news of 2019** so far into one handy document for you.

Digital therapeutics are accelerating towards the healthcare mainstream and this year has already been crucial to this.

Happy reading!

Jason



Jason Green
Head of the DTx Series



January: Otsuka and Click Therapeutics Collaborate

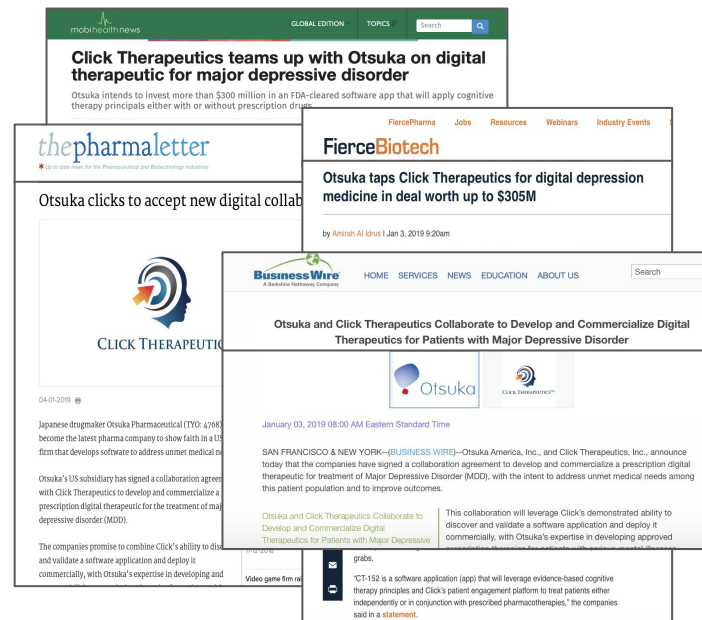
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January started with a bang as it was announced Otsuka and Click Therapeutics signed a collaboration agreement to develop and commercialise Digital Therapeutics for Patients with Major Depressive Disorder.

This approach has combined Click's proven ability to discover and deploy new software applications with Otsuka's expertise in developing and commercialising mental health treatments.

[You can view the press release here.](#)



January: Pear Therapeutics Completes Series C Funding of \$64m

2



Early January saw Pear Therapeutics successfully close a \$64 million Series C financing.

This cross-disciplinary financing will allow Pear to globally commercialise their prescription digital therapeutics and advance their clinical-stage pipeline.

[View the announcement here](#)



January: Kaia Health Secures \$10m in Series A Funding

3

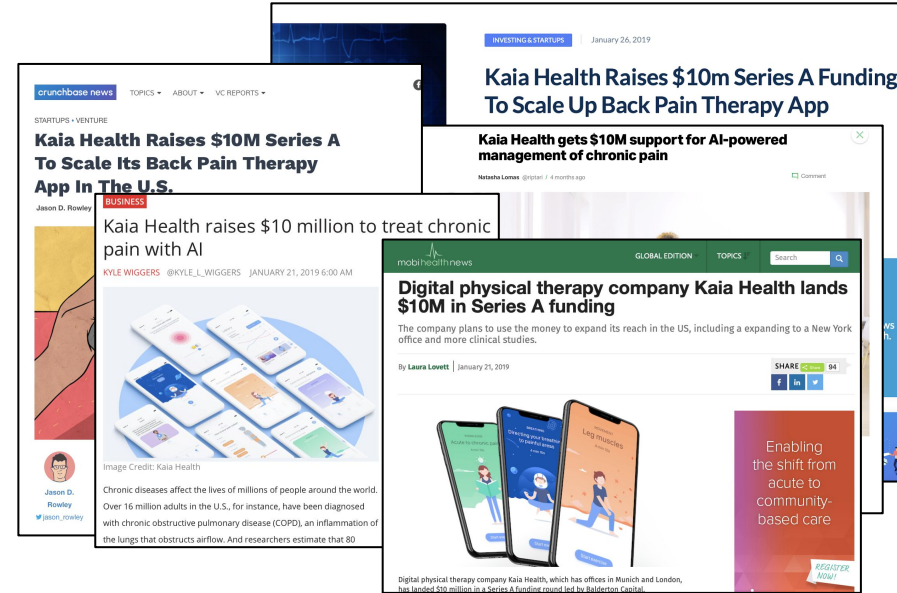
kaia

January saw more exciting DTx funding news!

Kaia Health raised \$10 million in Series A funding, led by Balderton Capital.

This funding will be used to fund further clinical studies and to scale its app-based, chronic pain therapy to the U.S.

[Read more here](#)



February: Cognoa Recieved FDA Breakthrough Designations

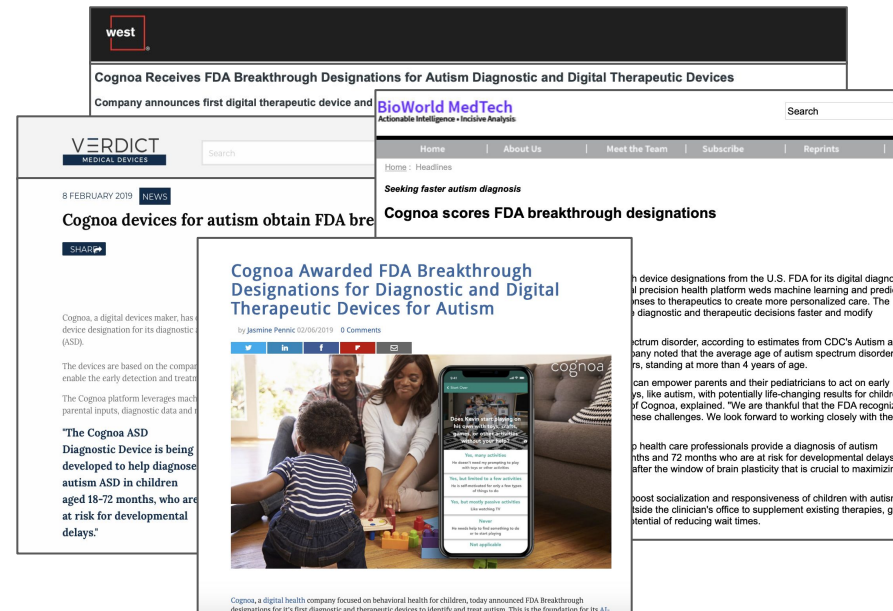
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cognoa

February got off to a great start, particularly for Cognoa!

The company announced that the FDA had granted Breakthrough Device designations for its lead products, the first digital therapeutic and digital diagnostic devices for autism.

[Read the press release here](#)



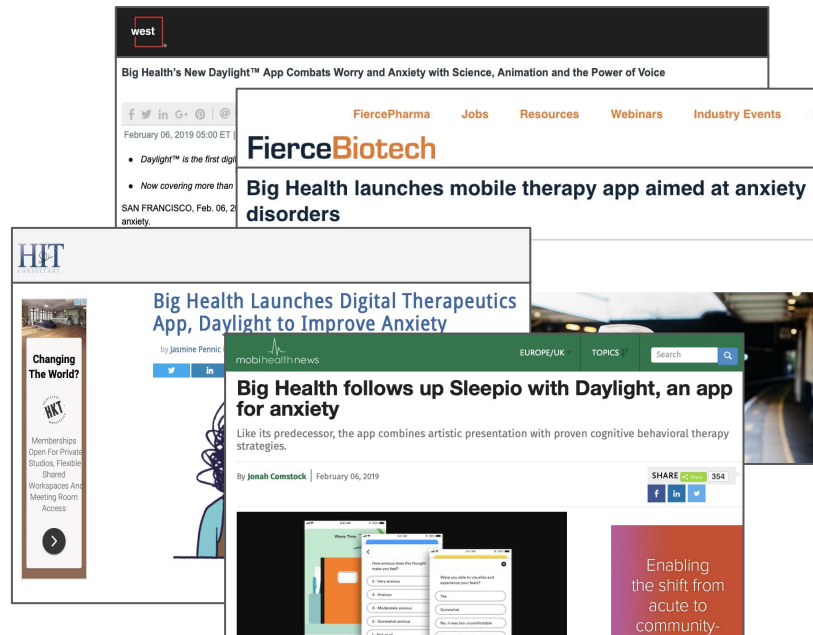
Big Health

In February Big Health launched its new product, Daylight™.

Daylight™ is a CBT-based app focused on combating and reducing feelings of worry and anxiety.

Following the success of their first product, Sleepio™ (a sleep improvement app), Big Health's newest product has the potential to help many more people back to good mental health.

[Check out the press release here](#)



February: Orion and Propeller Health Partner

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Propeller Health and Orion Corporation announced a partnership in February to bring new digital medicines for people with COPD and asthma.

This partnership will connect Orion's existing Easyhaler® line of inhalers with Propeller's digital medicine platform via a small sensor.

Orion serves patients across many European countries, so this partnership will expand Propeller's European presence.

[View the announcement here.](#)



March: Akili and Shionogi Partner to Commercialise in Asian Markets

7

AKILI

SHIONOGI INC.

In early March, [Akili and Shionogi announced they were teaming up](#), in an exciting partnership worth \$125 million.

In exchange for \$20 million upfront Shionogi will have the rights to the marketing, clinical development and regulatory filings for AKL-T01 and AKL-T02 (Akili's two leading DTx products) in Taiwan and Japan, while Akili will be eligible to receive royalties of up to \$105 million.

This strategic collaboration will help bring the first prescription digital therapeutics to Asian markets.

FierceBiotech

Akili and Shionogi pair up to bring digital therapies to Japan and Taiwan in \$125M deal

thepharmaletter

Up to date news for the Pharmaceutical and Biotechnology industries

Akili partners with Shionogi on digital therapeutics in certain Asian markets

MedCityNews

STARTUPS, CONVERGENCE, PHARMA

Digital therapeutics startup Akili Interactive inks deal with Japanese pharma company

In exchange for \$20 million upfront, Shionogi will have the rights to the marketing, clinical development and regulatory filings for AKL-T01 and AKL-T02 (Akili's two leading DTx products) in Taiwan and Japan, while Akili will be eligible to receive royalties of up to \$105 million.

By KEVIN TRUONG

PRESS RELEASE

Akili and Shionogi Announce Strategic Partnership to Develop and Commercialize Digital Therapeutics in Key Asian Markets

Published: Mar 7, 2019 2:00 a.m. ET

f t i y p

Akili to Create First-of-its-kind International Digital Medicine Development and Commercial Platform Shionogi to Oversee Clinical Development, Sales and Marketing for ADHD and Autism Spectrum Disorder Digital Therapeutics in Japan and Taiwan Upfront and potential milestone payments for Japan and Taiwan commercialization valued up to \$125 million

mobihdnews

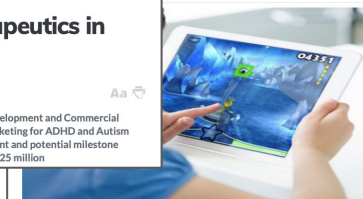
GLOBAL EDITION

TOPICS

Search

Akili hands off east Asia sales, clinical development, marketing of digital therapeutics to Japanese pharma

Of note, the deal specifies that Akili will still control the rollout and support of its video game-like treatments through a contract-based digital distribution platform.



Boston-based Akili Interactive Labs, maker of video game-like treatments for children with ADHD and autism spectrum disorder, has found a partner to help promote its digital

DTx

March: Kaia Health Outperforms Standard Physiotherapy

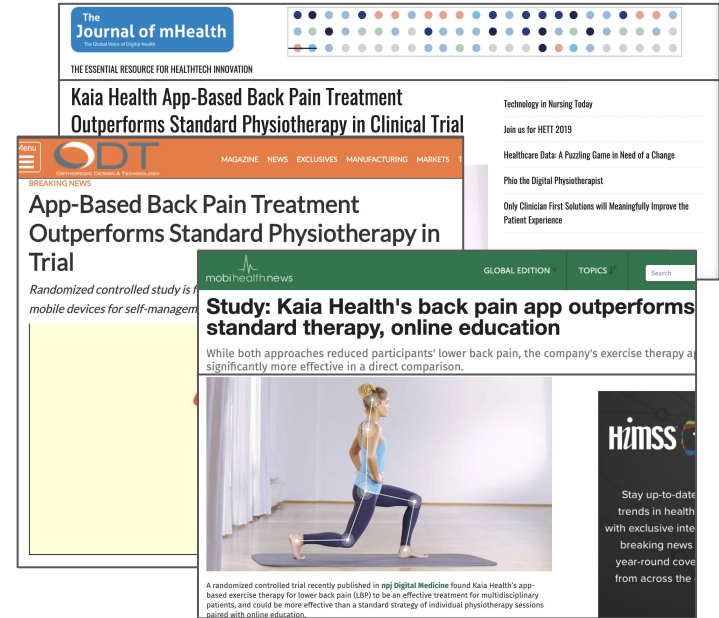
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kaia

In a landmark study, Kaia Health announced the results of its first randomized controlled trial of its app-based therapy for patients with non-specific low back pain.

The study, published in NPJ Digital Medicine reported significantly lower pain levels compared to the control group receiving physiotherapy and online education.

[View the press release here](#)



May: Happify Health Partners with Sanofi

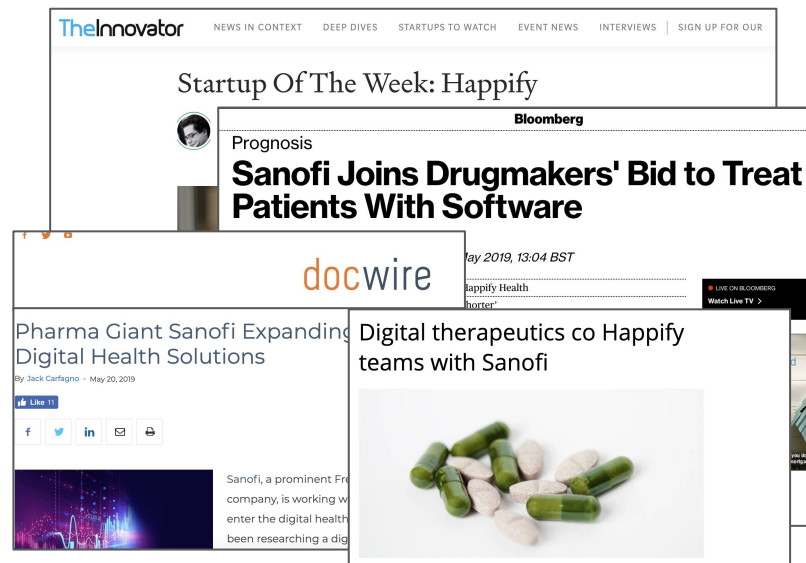
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Happify and Sanofi hit the headlines in May with the announcement of their partnership to explore digital therapies for patients with depression and multiple sclerosis.

This collaboration advances the trend of large pharma and digital therapeutic companies working together to improve the lives of patients with difficult to treat conditions.

[View the announcement here](#)

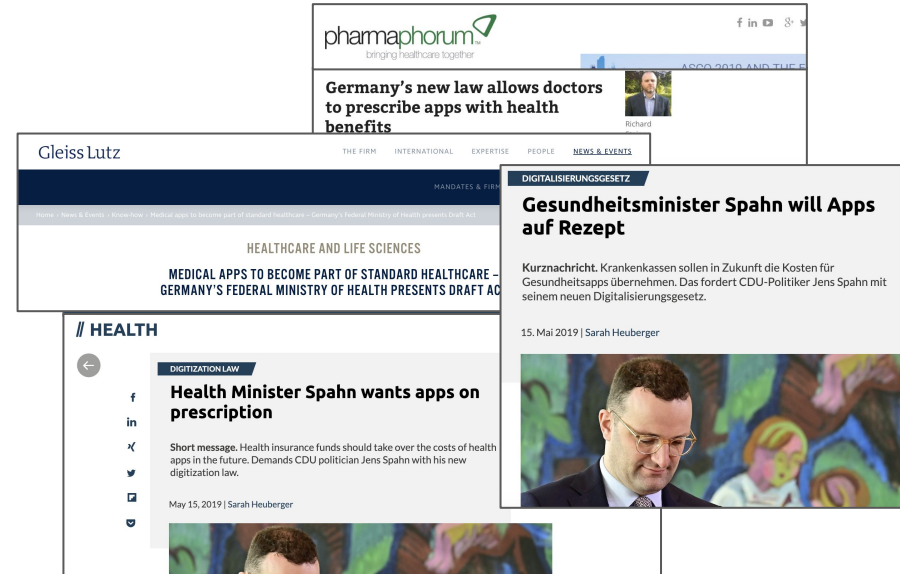


German Ministry of Health

In a significant country-wide step forward, the German Ministry of Health (BMG) announced its draft bill for legislation that will cover reimbursement of digital therapy software.

In a process that is set to be similar to drug reimbursement, evidence will be paramount and all payers in Germany will be obliged to reimburse after the decision by the BfArM (Federal Institute for Drugs and Medical Devices).

[View the announcement in German here](#)



May: Express Scripts Announces Launch of Digital Health Formulary

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EXPRESS SCRIPTS®

Yet more huge news as Express Scripts announces the launch of their Digital Health Formulary.

Set to be available in 2020, the formulary will be similar to a drug formulary and will feature a curated list of tech- and software-enabled applications and devices.

This is also set to help streamline the number of digital health tools for payers and providers.

[Find out more information here](#)

FierceHealthcare

Express Scripts to launch digital health formulary for payers, patients

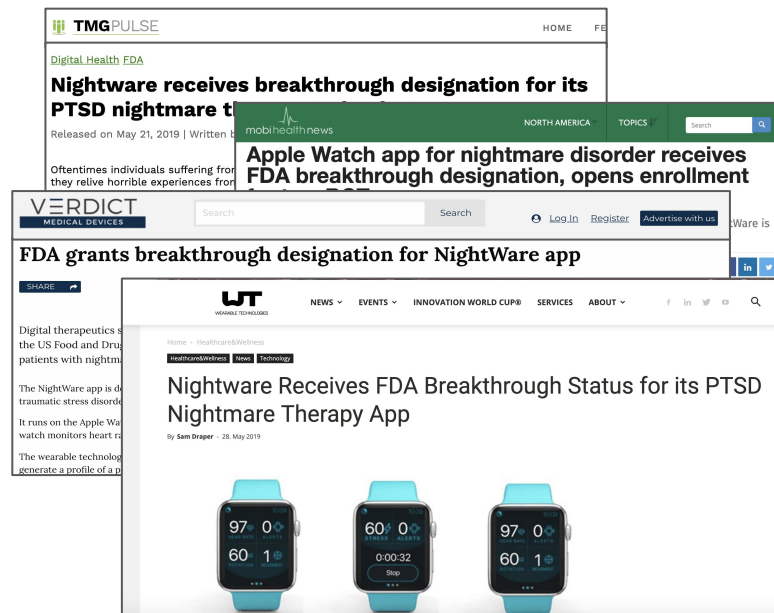


NightWare™

May was clearly the month for announcements, as NightWare's Apple Watch based digital therapeutic for PTSD patients affected by nightmares receives FDA Breakthrough Designation.

In addition to this, NightWare opened enrollment for two randomized controlled trials to drive their product through the pipeline.

[Find out more information here](#)



June: MedRhythms, Inc and Health Catalyst Partner

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In the first of three significant announcements on the same day (June 11th), MedRhythms partners with Health Catalyst to provide stroke survivors with access to their digital therapeutic.

The partnership aims to select patients who could benefit from the “rhythmic auditory stimulation”-based digital therapeutic, accurately measure their clinical outcomes and integrate the treatment into provider clinical workflow.

[Take a look at the press release here](#)



June: Big Health Partners with CVS Health

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Big Health

CVS unveiled its Vendor Benefit Management with the announcement that Big Health's Sleepio would be the first product offered on this service.

In a huge step forward for potential broader adoption and reimbursement of digital therapeutics, CVS Health will provide Pharmacy Benefit Management (PBM) clients access to digital and non-digital solutions. This will enable Sleepio to reach hundreds of thousands of Americans who may need help battling sleeplessness.

[Find out more information here](#)



**CVS Health Partners
with Big Health to
Help PBM Clients
Manage Health and
Wellness Benefit
Solutions**

June: Neurotrack Raises \$21M Series C Funding

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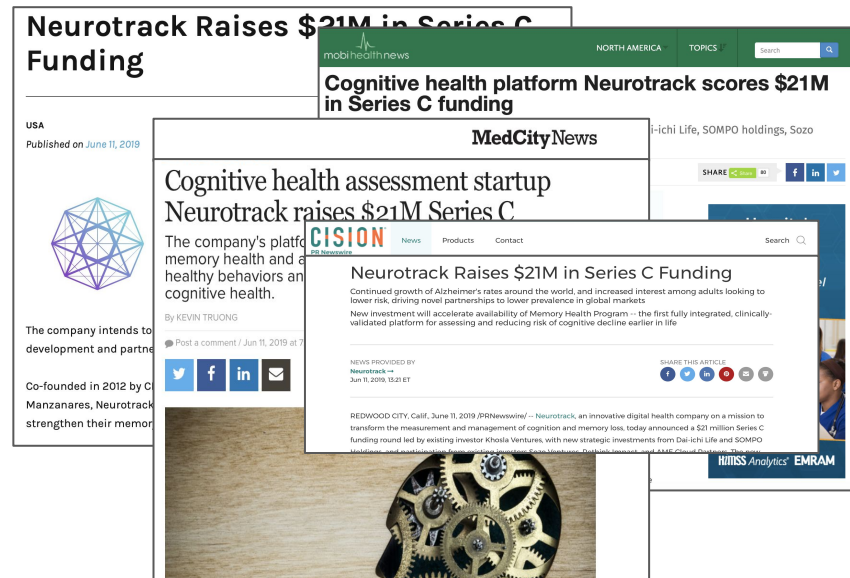
Neurotrack

The final piece of news on June 11th was that Neurotrack raised \$21M in Series C funding.

This round of funding will help Neurotrack commercialize its Memory Health Program and expansion into global markets.

[Take a look at the press release here](#)

June 11th is up there with the most important days in the history of digital therapeutics!

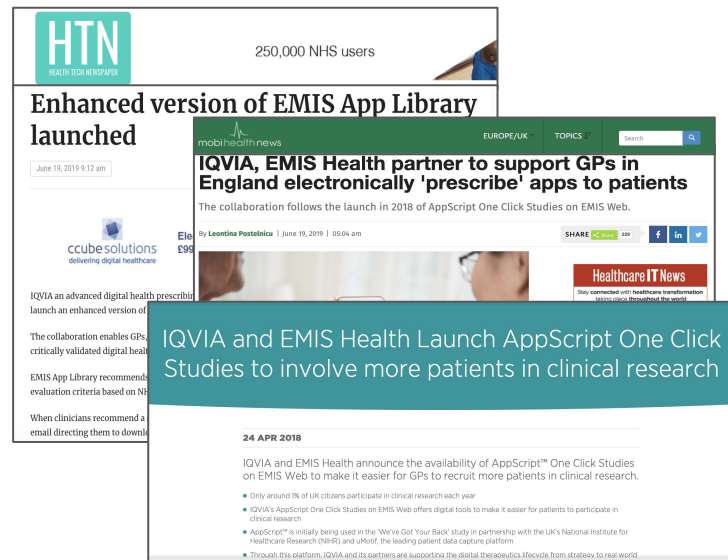




Off the back of the launch of AppScript One Click Studies in 2018, IQVIA partnered with EMIS Health to support Physicians in England electronically prescribe digital health apps to patients.

IQVIA will populate the EMIS App Library by evaluating apps against the NHS' evidence standards guidelines.

[View more details here](#)



July: FDA Validates Streamlined Review of SaMD - Pear First to Submit

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FDA

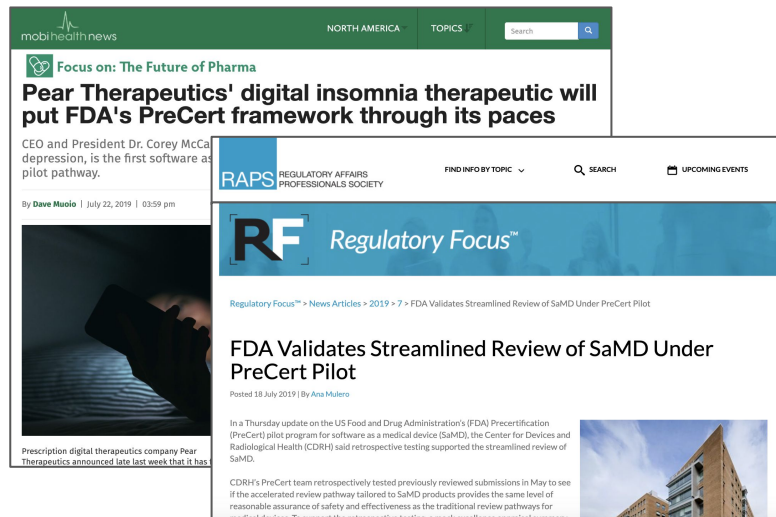


In July, the FDA announced the validation of their streamlined review process of Software as a Medical Device (SaMD) under its PreCert Program.

Pear swiftly followed this by announcing the submission of their digital therapeutic (Somryst) for chronic insomnia and depression, which is the first product to be submitted through the updated PreCert program.

[Read the FDA Announcement here](#)

[Read Pear Therapeutics Announcement here](#)



July: Korea Regulator Approves First Clinical Trial of Digital Therapeutic - Nunap

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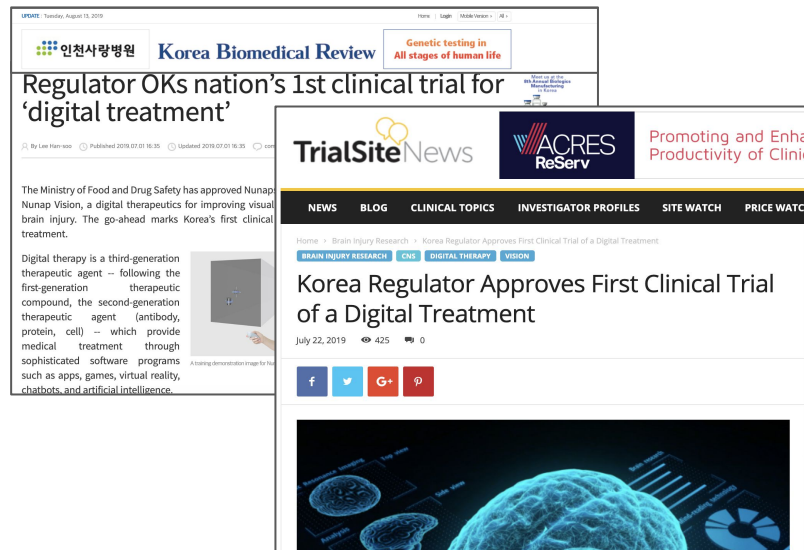
Korean Ministry of Food and Drug Safety



Digital therapeutics are going global and this is evident by the announcement in July that Korea's Ministry of Food and Drug Safety approved Nunaps' clinical trial of Nunap Vision.

This digital therapeutic is targeting patients with visual disorders after brain injury.

[Find out more information here](#)



July: Walgreen's Find Care Platform Expands to Include Propeller Health

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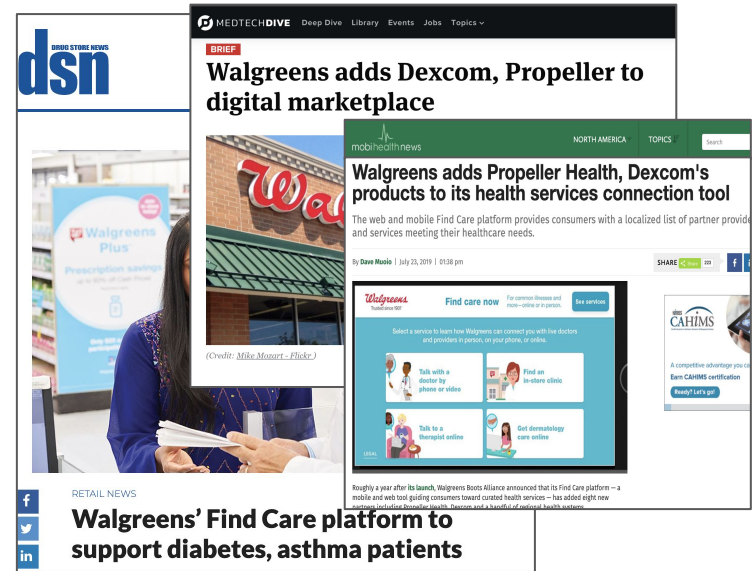
Walgreens



The good news continued rolling in July as Walgreen's announced that it's Find Care Platform would also now include Propeller Health's Digital Therapeutic for patients COPD.

The goal of this platform is to allow users to learn about and enroll for treatments such as Propellers.

[Find out more information here](#)



July: Voluntis Announces Market Authorization for Oncology Digital Therapeutic

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Closing out July, Voluntis announced that it has successfully completed an FDA review of Oleena™, its software for oncology-related symptom management and remote patient monitoring.

Oleen™ is determined as a Class II medical device that will support patients across a wide range of cancer diagnoses and anticancer treatments.

[Take a look at the press release here](#)



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